Patient-reported Outcomes of Removable Partial Denture Treatment

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Dedicated to my parents for being my source of inspiration, support and encouragement throughout my life,

to my husband with profound gratitude for his constant support and being one of a kind friend, and to my kids for their true love and laughter that made my days

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Authors contributions and Statement of Originality

This thesis contains three manuscripts, two are original research and one systematic review paper prepared by the candidate as the first author. One manuscript was published and the two others are ready for submission in peer-reviewed journals. A summary of the work originality and authors contribution is clarified below:

1. **Patient-reported outcomes of metal and acrylic resin removable partial dentures: a systematic review and meta-analysis**

Authors: Balqees Almufleh, Aminah Alesawy, Rania Rodan, Martin Morris, Mayumi Umebayashi, Elham Emami, Faleh Tamimi

Contribution: B.A. designed the protocol, performed the manual search, the update search and the search for grey literature, screened the studies, extracted the data, analyze the data, prepared the manuscript. A.A. and R.R. screened the studies and extracted the data as second reviewers, M.M. prepared the search strategy and performed the electronic search, M.U. translated the Japanese studies and extracted the data, E.E. and F.T. supervised all steps of the project and reviewed the manuscript.

Originality: This is the first systematic review that synthesized the evidence on the patient-reported outcomes of metal and acrylic resin removable partial dentures. It identified the current level of evidence on this comparison and indicated the weaknesses of available literature. It directed researchers towards potential areas of research in this clinical topic.

2. **Patient satisfaction with laser-sintered removable partial dentures: A crossover pilot clinical trial**

Authors: Balqees Almufleh, Elham Emami, Omar Alageel, Fabiana de Melo, Francois Seng, Eric Caron, Samer Abi Nader, Ashwaq Al-Hashedi, Rubens Albuquerque, Jocelyne Feine, Faleh Tamimi

Contribution: B.A. participated in the study design, collected the data, analyzed the data and prepared the manuscript, E.E.: supervised the study and reviewed the manuscript, O.A. collected the data, F. M. collected the data, F.S. Helped in patients recruitment, E.C. directed the laboratory part of the study, S.A.N helped in the study design, A.A. helped in the study design, R.A. designed the study, J.F. helped in the data analysis, F.T. designed the study, supervised the study and reviewed the manuscript.

Originality: This is the first clinical trial to evaluate the clinical performance of laser-sintered removable partial dentures. It assessed the clinical performance of laser-sintered removable partial dentures in terms of patient satisfaction and compared it with the traditional cast removable partial dentures. Findings from this study helped clinicians during treatment planning and direct researchers towards the potential benefits of this new technology in improving patient satisfaction with removable partial dentures.

3. **Tooth shade preferences among the general public**

Authors: Balqees Almufleh, Elham Emami, Aliaa Al-Khateeb, Stefano Del Monte, Faleh Tamimi

Contribution: B.A. designed the study, designed the surveys, collected the data, analyzed the data, prepared the manuscript, A.A. and S.D.M. designed the study, designed the first survey and collected the data, E.E. supervised the study and reviewed the manuscript, and F.T. designed the study, supervised the study and reviewed the manuscript.

Originality: This is the first study to provide information regarding North American preferences in terms of tooth shade. It also evaluated the effect of skin shade of the patients and several observer-related variables (age, sex, education, dental affiliation) on people preferences of tooth shade. The findings of this study are expected to help dentists during tooth shade selection in dental practice.

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RPD	Removable partial denture
PPA	Removable partial denture
OHRQoL	Oral health-related quality of life
PMMA	Polymethyl metha acrylate
ADA	American Dental Association
CAD	Computer-aided design
CAM	Computer-aided manufacturing
3D	Three-dimensional
DLP	Digital Light Processing
USA	United States of America
ROBINS-I	Risk of Bias in Non-randomized Studies of Interventions
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
ASA	American Society of Anesthesiology
CONSORT	Consolidated Standards Of Reporting Trials
STL	Standard Tessellation Language
M	Male
F	Female
U	Upper/maxillary arch
L	Lower/mandibular arch
CD	Complete denture
NT	Natural teeth
Ant.	Anterior teeth
Post.	Posterior
NR	Not reported
LS	Laser-sintered denture
ND	No difference

MD	Mean difference
CI	Confidence interval
SD	Standard Deviation
SE	Standard Error
OR	Odds ratio
VAS	Visual Analog Scale
NI	No information
NA	Not applicable
OHIP	Oral Health Impact Profile
NIDCR	National Institute of Dental and Craniofacial Research

Abstract

Removable partial denture (RPD) treatment is an affordable, non-invasive treatment for partially edentulous patients. It is the most commonly used treatment for elderly populations who are growing due to the increased life span in developed countries. Although RPD can successfully improve patients mastication, esthetics and phonetics, they are associated with high dissatisfaction and noncompliance.

Hypotheses: Null hypothesis is that material and technique used for RPD fabrication have no effect on patient-reported outcomes of RPD treatment. The aim of this thesis was to evaluate the effect of the material and technique used for RPD fabrication on patient-reported outcomes of RPD treatment in three different studies. More specifically, we aimed to assess the clinical impact of acrylic resin, and cast and 3D-printed metal dentures and to identify the most popular tooth shade for restoring anterior teeth.

Methods: To assess the effect of denture base material, a systematic review and meta-analysis was conducted comparing patient-reported outcomes between metal and acrylic resin RPDs. To assess the effect of denture fabrication techniques, a pilot crossover randomized clinical trial was conducted to compare cast with 3D-printed metal RPDs. Patients (n=12) were assigned randomly to wear RPDs made with casting and 3D-printing on alternate periods of 30 days. Patient satisfaction was measured using McGill Denture Satisfaction Instrument after 4 weeks of follow-ups. Linear mixed effects regression models were used to analyse the data using the intention-to-treat principle. To assess people preferences of tooth shade, a cross sectional survey study was conducted. Two online surveys using computer-designed perioral images of different shades of the skin and teeth were conducted, the first survey assessed individual preferences of tooth shade

value, hue and chroma as a function of the skin shade, the second survey aimed to pinpoint the most preferred tooth shade. Logistic regression was used to determine significant predictors of preferred tooth shades.

Results: In the systematic review, out of the 4056 studies screened, a total of 15 studies were included in the systematic review (6 for patient satisfaction, 5 for OHRQoL, 3 for patient compliance and 1 for denture preference), and 10 in the meta-analysis. Pooled effect size of patient satisfaction and oral health-related quality of life showed that there was no significant difference between metal and acrylic resin RPDs, while the pooled effect size of patient compliance showed that metal dentures were significantly associated with higher patient compliance compared to acrylic resin RPDs. Moreover, the one study on denture preference showed that metal RPD was more preferred over acrylic resin RPD. However, most studies had critical to serious risk of bias and low level of evidence.

The pilot clinical trial on RPD fabrication methods showed significant advantages of 3D-printing over the traditional manual casting technique. Patients were significantly more satisfied with 3D-printed compared to cast prostheses in regard to general satisfaction, ability to speak, ability to clean, comfort, ability to chew, chewing efficiency and oral condition ($P<0.05$). The cross-sectional survey on tooth shade preferences showed that most of the participants preferred teeth with the highest value (54%), a neutral hue (59%) and the lowest chroma (89%). Most participants (75%) preferred the lightest tooth shade (1M1), regardless of the model skin color ($p<.001$).

Conclusion:

1. Only low evidence exist on patient-reported outcomes comparing metal to acrylic resin RPDs, and showed that there was no significant difference between metal and acrylic resin dentures in terms of patient satisfaction and oral health-related quality of life.

2. Our clinical trial showed that using 3D-printing fabrication method may lead to better outcome in terms of patient satisfaction in the short term compared to casting method for RPDs.
3. Teeth with high value, neutral hue and low chroma were the most preferred. The 1M1 was the most preferred tooth shade regardless of skin shade.

Résumé

Le traitement par prothèse partielle amovible (PPA) est un traitement abordable et non invasif pour les patients partiellement édentés. Il s'agit du traitement le plus couramment utilisé chez les populations âgées, qui se développent en raison de la longévité accrue des pays développés. Bien que les PPA puissent améliorer avec succès la mastication, l'esthétique et la phonétique des patients, elles sont associées à un taux élevé d'insatisfaction et de non-conformité.

Hypothèses: L'hypothèse nulle est que le matériau et la technique utilisés pour la fabrication de la PPA n'ont aucun effet sur les résultats du traitement de la PPA rapportés par les patients. Le but de cette thèse était d'évaluer l'effet du matériau et de la technique utilisés pour la fabrication de la PPA sur les résultats du traitement de la PPA rapportés par les patients dans trois études différentes. Plus spécifiquement, nous avons cherché à évaluer l'impact clinique des prothèses métalliques en acrylique, moulées et imprimées en 3D et à identifier la teinte de dent la plus populaire pour la restauration des dents antérieures.

Méthodes: Pour évaluer l'effet du matériau de base de la prothèse dentaire, une revue systématique et une méta-analyse ont été conduites pour comparer les résultats rapportés par les patients entre les PPAs en métal et en acrylique. Pour évaluer l'effet des techniques de fabrication des prothèses, un essai clinique pilote croisé randomisé a été mené afin de comparer le moulage avec des PPAs métalliques imprimées en 3D. Les patients (n = 12) ont été assignés au hasard à porter des PPAs avec moulage et impression 3D alternant périodes de 30 jours. La satisfaction des patients a été mesurée à l'aide de l'instrument de satisfaction des prothèses de McGill après quatre semaines de suivi. Des modèles de régression linéaire à effets mixtes ont été utilisés pour analyser les données à l'aide du principe de l'intention de traiter. Pour évaluer les

préférences des personnes en ce qui concerne la teinte des dents, une enquête transversale a été réalisée. Deux enquêtes en ligne utilisant des images périorales conçues par ordinateur de différentes teintes de la peau et des dents ont été menées. ombre de dent préféré. La régression logistique a été utilisée pour déterminer les prédicteurs significatifs des nuances de dents préférées.

Résultats: Dans la revue systématique, sur les 4056 études examinées, 15 études au total ont été incluses dans la revue systématique (6 pour la satisfaction des patients, 5 pour la OHRQoL, 3 pour la compliance du patient et 1 pour la préférence pour les prothèses), et 10 dans la méta-analyse. La taille combinée de la satisfaction du patient et de la qualité de vie liée à la santé bucco-dentaire a montré qu'il n'y avait pas de différence significative entre les PPA en métal et en acrylique, tandis que la taille combinée de l'observance du patient a montré que les prothèses métalliques étaient associées de manière significative à une meilleure observance du patient par rapport à l'acrylique. En outre, une étude sur les préférences des dentiers a montré que la PPA métallique était plus préférée que l'acrylique. Cependant, la plupart des études présentaient un risque de biais grave et un niveau de preuve faible au potentiel grave.

L'essai clinique pilote sur les méthodes de fabrication de PPA a montré des avantages significatifs de l'impression 3D par rapport à la technique de coulée manuelle traditionnelle. Les patients étaient nettement plus satisfaits des prothèses imprimées en 3D que des prothèses coulées en ce qui concerne la satisfaction générale, la capacité de parler, la capacité de nettoyage, le confort, la capacité de mâcher, l'efficacité de la mastication et l'état buccal ($P < 0,05$). L'enquête transversale sur les préférences de teinte des dents a montré que la plupart des participants préféraient les dents avec la valeur la plus élevée (54%), une teinte neutre (59%) et la chroma la plus faible (89%). La

plupart des participants (75%) ont préféré la teinte de dent la plus claire (1M1), quelle que soit la couleur de la peau du modèle (p <0,001).

Conclusion:

1. Seules peu de données probantes sur les résultats rapportés par les patients comparant les PPA en métal à acryliques et ont montré qu'il n'y avait pas de différence significative entre les prothèses en métal et en acrylique en termes de satisfaction du patient et de qualité de vie liée à la santé bucco-dentaire.

2. Notre essai clinique a montré que l'utilisation de la méthode de fabrication par impression 3D pouvait conduire à de meilleurs résultats en termes de satisfaction du patient à court terme par rapport à la méthode de moulage pour les PPA.

3. Les dents avec une valeur élevée, une teinte neutre et une chroma faible étaient les plus préférées. La teinte 1M1 était la teinte préférée des dents, quelle que soit leur teinte.

Chapter One: Introduction

1.1 **Thesis outline**

This thesis is prepared in a manuscript-based format following McGill University Thesis Preparation Guidelines. It consists of nine chapters. Chapter one presents an introduction to the thesis, research rationale, thesis hypothesis and objectives. Chapter two reviews the literature of patient-reported outcomes for removable partial denture wearers. Chapter three presents a brief about the methodology used in the research part of this thesis. Chapters four, five and six present the three research manuscripts of the thesis. Chapter seven discusses the findings, the clinical significance and limitations of the research projects included in this thesis. Chapter eight provides the overall global conclusions. Chapter nine lists all references used in the thesis. Appendices include the questionnaires used in this thesis projects, and the ethical approval documents concerning the projects in this thesis.

1.2 **Thesis research rationale, hypothesis and objectives**

The removable partial denture is a widely used treatment option to restore partially edentulous patients [1]. It can restore function and improve patients quality of life [2], however removable partial dentures are associated with high dissatisfaction rates and high denture discard rates [3-5]. Factors influencing patients satisfaction with removable partial dentures could be classified into three types: clinician-related, patient-related and denture-related factors. Clinician-related factors include clinical experience and knowledge of the clinician. Patient-related factors that showed significant association with patient satisfaction include; patient age, general health status, previous experience with removable partial denture, type of restoration on the opposing arch, Kennedy classification of

edentulism, and number and location of restored teeth [4, 6-8]. Denture-related factors include denture material, fabrication technique, denture design, and artificial tooth color, shape and size [6, 8, 9]

We have limited control on the clinician-related and patient-related factors, however we have more control on denture-related factors, and therefore they could be targeted to enhance the patients perceptions of removable partial denture. Accordingly, the influence of denture-related factors on patient satisfaction with removable partial denture was the focus of this thesis. Among denture-related factors, it is expected that denture material and fabrication process could significantly affect the future quality of removable partial denture treatment by reducing costs and increasing patient satisfaction and compliance [6].

We hypothesize that the denture material properties and denture fabrication process could influence the patient-reported outcomes of removable partial dentures.

Removable partial dentures are fabricated traditionally using lost-wax technique, which is heavily prone to human-errors [10-12]. Nowadays, removable partial dentures can be produced digitally using 3D-printing [13, 14]. This technique improves fabrication, reduces time and waste, and could provide more accurate prostheses [13, 14], and it has shown promising clinical results for fixed restorations and complete denture treatments [13, 15, 16]. Building on this knowledge, *our first specific hypothesis was that the denture fabrication process could influence patient-reported outcomes of removable partial denture.*

Two types of materials are mainly used to fabricate removable partial dentures; metal alloys and polymers [6]. Although clinical guidelines recommend using cast metal removable partial denture as long-term treatment option and acrylic resin denture as interim

denture, evidence regarding the superiority of metal dentures over acrylic resin has not been synthesized yet [17]. Therefore, *our second specific hypothesis is that denture material could have an effect on patient-reported outcomes of removable partial dentures.*

Another property related to the denture material is the color of artificial teeth included in the denture. One of the reasons for removable partial denture being discarded is dissatisfaction with esthetics [5]. Among all components of esthetic smile, tooth color seems to be considered by the general population as the most important factor determining smile esthetics [18-20]. Whenever possible, adjacent teeth are used as a guide for tooth shade selection, however, when a denture is replacing all anterior teeth, other landmarks are used. Skin color is the most common guide used clinically [21]. However, clinical studies found that the association between skin and tooth color is weak and inconsistent in different populations [22, 23]. Therefore in the lack of strong evidence, the latest guidelines recommend listening to the patient preferences as the first and most important step in shade selection [24]. Current literature is lacking in regard to patients' perception of esthetic tooth shade for different skin shade of the face using clinically meaningful shade guides. Therefore, our *third specific hypothesis is that tooth shade preference is affected by the skin shade of the face.*

In order to assess the main hypothesis and the specific hypotheses of this thesis, the main aim was to assess the influence of denture material properties and denture fabrication on patient-reported outcomes of removable partial denture treatment.

The specific objectives of this thesis are:

1. To assess how the material used for removable partial dentures fabrication influence patient-reported outcomes (patient satisfaction, oral health-related quality of life, and denture preference)

2. To assess how 3D-printing fabrication process influences patient satisfaction with removable partial dentures

3. To identify laypersons' most preferred tooth shade as a function of observer and patient factors.

Chapter Two: Background and literature review

2.1 Partial edentulism

2.1.1. Epidemiology:

Despite the significant decrease in the rate of edentulism in industrialized countries, the prevalence of tooth loss and partial edentulism will continue to grow due to the increased life expectancy and the current aging trend [25]. Prevalence of partial edentulism ranges from 30% to 60% among Europeans over the age of 65 [25]. In the UK, it is expected that approximately 96% of adults will be at least partially dentate by 2028 [26]. A similar trend has been shown in Germany and Japan too [26], and in Brazil, about 35.6% of the population has been shown to have less than 20 teeth in the mouth [27, 28].

2.1.2. Etiology and Disease burden

There are several causes for partial tooth loss, which include caries, periodontal diseases, traumatic injuries and other reasons related to required dental treatment like pre-prosthetic or orthodontic reasons. Caries followed by periodontal diseases are considered the two most common reasons for tooth loss [29]. First and second molars are the most commonly extracted teeth [29]. In a Brazilian study, caries was the main reason for tooth extraction (63%), followed by periodontal disease (13%) and orthodontic reasons (12%). Less common reasons for tooth extraction were pre-prosthetic reasons (3.2%), pericoronitis (0.4%) and trauma (0.2%) [30].

In Kuwait, caries (43%) and periodontal disease (37.4%) were the two most common causes of tooth extraction. Caries was considered the most common reason for tooth extraction before the age of 40, while periodontal disease was the most common reason for tooth extraction in the older population [31]. A similar pattern was identified in Japan where caries was the most frequent reason of tooth extraction (55%), followed by periodontal disease (38%) [32]. Among males, periodontal disease was the most common reason for tooth extraction, while among females caries was the most common reason [32]. Moreover, periodontal disease was the most common reason for extraction of mandibular anterior teeth [32].

Tooth loss has been associated with several negative sequalae including resorption of the alveolar process, drifting of adjacent teeth and extrusion of opposing teeth (if present). Depending on the number and location of teeth lost, vertical occlusal stops might be lost which could lead to teeth intrusion, attrition and labial tilting of the anterior segment specially in the maxilla [33].

Studies showed that a minimum of 20 teeth with nine to ten pairs of contacting units (including anterior teeth) is associated with adequate masticatory efficiency (comminution efficiency) and masticatory ability (self-reported mastication). Individuals with less than that level had poorer masticatory efficiency than people with 20 teeth or more [34]. For most people, three to four units of functional posterior teeth are sufficient to obtain occlusal support and stability in case of symmetrical pattern of tooth loss, or five to six units in case of asymmetrical pattern [34]. Moreover, tooth loss has been associated with compromised phonetics function [35].

Oral health-related quality of life (OHRQoL) is also affected by tooth loss; a deterioration of OHRQoL is directly correlated with the number of teeth lost. Moreover, a study showed that anterior tooth loss is associated with more deterioration in OHRQoL compared with posterior tooth loss [36].

Tooth loss has implications on the overall general health. It has been associated with restricted dietary choices which might lead to nutritional imbalance [37]. Moreover, tooth loss has been associated with an increased risk of cognitive impairment and dementia. A recent systematic review has shown that individuals with suboptimal dentition (< 20 teeth) were associated with a 20% higher risk of developing cognitive impairment than those with optimal dentition [38]. The participants of the studies included in this review, had an average age ranging from 45 to 88 years, and presented several comorbidities such as diabetes, depressive symptoms, hypertension, history of vascular diseases, stroke, rheumatoid arthritis, cancer, head trauma, and family history of dementia. Follow-up time ranged from 4 to 20 years [38].

2.1.3 Treatment options of partial edentulism

Several treatment options are available for restoring partial edentulism, which include implant-supported crowns, implant-supported fixed partial dentures, removable partial dentures (RPD), and tooth-supported fixed partial dentures (FPD). A recent systematic review analyzed the impact of different treatment options of partial edentulism on OHRQoL. It showed that the greatest improvement in OHRQoL is achieved with implant-supported FPD, followed by tooth-supported FPD. Removable partial denture achieved reasonable improvement in OHRQoL shortly after treatment but insignificant improvement after long term use [39].

Despite the superior success rates and the clinical advantages of implant restorations for partial edentulism, removable partial dentures are still needed specially for the elderly populations. Several factors contribute to the continuous need for RPD including low socioeconomic status, poor access to health care, and compromised general health [1]. Moreover, there are some anatomical and psychological reasons that preclude patients from receiving dental implants [40, 41]. Even in rich countries like the United States, a large portion of the population does not have access to expensive dental treatments [26].

2.2 Removable partial dentures

Removable partial denture is a non-invasive simple treatment that restores patients function and esthetics, and improves the OHRQoL of partially edentulous population [2]. It has been shown that about 13-29% of European adults wear RPDs [1], and it is predicted that RPD treatments will consume minimum of 207 million hours of dentist' work per year in the United States in 2020 [42]. Although it has been reported that the use of RPDs in the United States has sharply declined from 1994 to 2002, this was not the case for the elderly group where the use of RPD has remained almost constant throughout this period [43].

Wearing RPD is strongly associated with age as the prevalence of wearing RPDs increases in older age groups [1]. In fact, in several European countries, the most common dental restorations used for the older population was RPDs [1]. In Switzerland in 2012, , about 43-59 % of people older than 75 years had RPDs, 36-45% had FPDs, and only 0.6-3 % had dental implants restored with removable or fixed restorations [44]. In Denmark, in the age group of 55 years or older, about 15% had RPDs while only 3.4% had FPDs [45].

Another factor associated with RPD use was missing the most posterior teeth. As the number of missing posterior teeth increases and the tooth loss is bilateral, the usage of RPD increases [46]. Removable partial denture was the most frequently offered treatment (92%) to restore cases of shortened dental arch in general dental practice in UK, while implants comprised only 5.7% [47].

2.3 Types of removable partial dentures

Removable partial dentures are classified based on the denture base materials into three classes; metal, acrylic resin and flexible RPDs.

2.3.1 Metal removable partial dentures

Since 1929, definitive RPD has been traditionally fabricated in cobalt chromium metal alloys, which is the most commonly used alloy for RPD framework fabrication. Other alloys used are nickel-chromium and more recently titanium alloys. However, due to the potential allergic responses and toxic effects related to the use of nickel-containing alloys in the oral cavity, nickel-chromium alloys are being avoided these days [48]. Cobalt-chromium alloys are classified as predominantly base metal alloys according to the ADA classification of dental casting alloys. The elemental composition of most of the commercial available dental alloys for RPD framework fabrication consists of about 62-65% cobalt, 25-29% chromium, and 5-6% molybdenum, and different trace elements in less than 1% by weight [48].

Metal RPDs are considered definitive treatment, and present several advantages [6]. Metals have high modulus of elasticity and thus as a denture base provide high strength and

stiffness which enables thin cross sections, and minimizes the covering of gingival margins. Metals also have high resistance to corrosion, tarnish and wear due to re-passivation [6]. Metals have high thermal conductivity which provides more natural experience to the patients and the underlying tissues [6].

On the other side, metal RPDs have several disadvantages including unesthetic metal display, metal taste, and hypersensitivity or adverse tissue reactions in sensitive patients [6]. Other disadvantages are related to the difficult fabrication technique and difficult adjustment and repair. Metal RPDs are traditionally fabricated using the lost wax technique which requires several steps, many materials and special equipment. Adjustment and repair of metal RPD could be performed by soldering, which is a highly sensitive procedure, making repair difficult and unpredictable [6].

2.3.2 Acrylic resin removable partial dentures

Acrylic resin has been used as a denture base material for RPDs since 1940. Among the acrylic resin polymers, poly methyl methacrylate is the most commonly used for RPDs fabrication. Acrylic resin RPDs are indicated to restore esthetics, phonetics and masticatory function and to maintain the integrity of oral tissues for a temporary period of time (few months) as an interim RPDs, that is eventually replaced by a final restoration [49].

Acrylic resin RPDs have several advantages including its optimum esthetics appearance, ease of fabrication with few clinical and laboratory steps, ease of adjustment and reline, its light weight and its low cost [6]. On the other hand, acrylic resin RPDs have several disadvantages some related to the properties of the resin material and some related to the traditional denture design used for acrylic resin RPDs.

Acrylic resin as a material has low mechanical strength including low flexural and impact strength, low thermal conductivity, brittleness, low elastic modulus, high coefficient of thermal expansion, high porosity, roughness, and water sorption [6, 50]. These properties resulted in the following clinical weaknesses associated with acrylic resin RPDs [6]:

- Weak and prone to fracture, need to be fabricated with a thick cross section to have adequate strength which might feel uncomfortable to patients
- Susceptible to staining
- Porosity and surface roughness caused increased area for plaque accumulation
- Release of unreacted monomers causing allergic reactions in sensitive patients
- Water sorption and solubility, which affects the dimensional stability and denture durability

Ideally, although acrylic resin RPDs are often prescribed for a temporary period of time, the fabrication of this prosthesis should be given equal concern as it is given to metal based dentures, i.e. designing this prosthesis should follow all biomechanical and biological guidelines for RPD design [51]. Preliminary casts should be surveyed and all necessary modification to the axial surfaces of abutments teeth adjacent to the edentulous span should be performed [51]. Gingival tissue should be left uncovered wherever possible to facilitate plaque removal and oral hygiene and to minimize damage to underlying tissues [52].

Traditionally, acrylic resin RPDs are usually fabricated as mucosa-borne tissue supported dentures with maximum soft tissue coverage for denture support, some wrought wires for denture retention, and without rests or guide planes [53]. Usually, acrylic resin RPD bases are fabricated with some interdental wedges that fit the interdental spaces palatally/lingually to provide some retention and help hold the denture secure in the patient

mouth. These wedges cover the gingival margins, and are believed to aggravate plaque accumulation and exert some lateral forces on the teeth which could probably accelerate periodontal breakdown [54]. In a study, the mean number of gingival margins covered by upper acrylic resin RPDs was about 8 gingival margins per denture which was four times that for upper metal RPD, which was about 2 gingival margins [55].

Being mucosa-borne, acrylic resin RPD lack rests which provide support against vertical displacement of the RPD against soft tissues. Without rests, acrylic resin RPDs tend to sink over the soft tissue and that is believed to increase the RPD damaging effects in terms of bone resorption, soft tissue inflammation and abutment teeth mobility. Moreover, it is thought that acrylic resin RPD settlement on soft tissue could lead to reduced denture acceptance by patients [52].

Clinical survey studies showed that acrylic resin RPDs have been used more frequently and for longer term than theoretically indicated [56, 57]. In fact, they comprise around 33 to 75% of RPDs provided to patients in different countries [56-58]. In some countries, only acrylic resin RPDs are covered by governmental health insurance, so it is the only accessible restoration for patients of lower socioeconomic status [5, 59]. While it is thought that long term use of acrylic resin RPDs could lead to damaging effects as they are indicated for interim use only, currently the evidence behind this belief has not been evaluated yet [60].

2.3.3 Flexible dentures

Around 1950, nylon-based ployamide RPDs (Valplast) were introduced in the United States and it gained popularity. Later, with the development of denture base fabrication techniques, other thermoplastic resins (polyamide, polyester, polycarbonate, and

polypropylene) were utilized to produce flexible RPDs [61]. Flexible RPDs have several advantages over metal RPDs, including improved esthetics, suitability for patients allergic to metal, light weight, flexibility, and cheaper price compared to metal RPDs [61].

Currently, there is insufficient evidence regarding the effectiveness of flexible RPDs although they are widely used in the market [61]. Compared to acrylic resin RPDs (20%), flexible RPDs were more preferred by patients (70%) due to their superior esthetics, speech and comfort on eating in a one month follow-up study [64]. In a study assessing anterior rehabilitation cases, patients with flexible RPDs scored higher OHRQoL compared to metal RPDs [65], however, in another study, metal RPDs patients scored significantly higher satisfaction than patients with flexible RPDs [66]. It seems that flexible dentures could be a promising esthetic RPD alternative, however, more clinical studies are needed before this treatment can be recommended [62].

2.4 Fabrication techniques for removable partial dentures

Metal removable partial dentures have been traditionally fabricated using the lost-wax technique, a very laborious manual process that is highly prone to human errors. Recently, CAD/CAM technologies have revolutionized the fabrication techniques of RPDs significantly cutting down production costs and time while maintaining and improving the quality.

2.4.1 Traditional cast metal removable partial dentures

Since their conception, RPDs have been traditionally made of cast alloys using the traditional lost-wax technique. This technique is able to produce RDP frameworks with

acceptable accuracy and acceptable clinical fit at average cost and productivity [6]. However, this technique has several disadvantages. It involves lengthy steps including manual construction of wax patterns for the designed prostheses frameworks, investing the patterns to form models, melting the wax to prepare the space, and then pouring the molten metal to the prepared space in the molds [10]. During this process, a large amount of materials and consumables are required, with limited capacity to recycle used materials [6].

This technique is also highly prone to human errors [10]. During the fabrication of RPD, there are 243 different types of errors that could occur, which in severe cases cause treatment failure. About 74% Of these errors are related to the laboratory steps which indicates the sensitivity and complexity of the lost wax technique and its susceptibility to human errors [10-12]. In a large population-based study, only about one third of RPDs worn by adults in USA had a satisfactory quality, which confirms the inherent limitations of the traditional fabrication technique of RPDs [63].

2.4.2 Digital removable partial dentures

The evolution of computer-aided design (CAD) and digital milling manufacturing marked a huge milestone in the fabrication of dental restorations. This technology reduces the time, cost, and human errors associated with the rehabilitation of fixed dental prostheses. However, milling manufacturing of removable partial dentures is difficult to accomplish due to the spatial restriction of the complex structure of RPD frameworks with its clasps, rests, and connectors, and uneconomical due to the high hardness of RPD alloys, which quickly wear the milling tools. Therefore, lost-wax casting has remained the standard technique for metal RPDs [13, 64], and although milling resin or wax patterns of the RPD frameworks are available in the market, they did not gain widespread popularity.

Stereolithography has been recently used to print the resin or wax sacrificial patterns of the RPD frameworks [65]. This processing produces frameworks with acceptable fit and reduces some of the costs and human errors associated with the manual wax-ups [66]. However, the printed resin pattern still has to be cast conventionally to get the final RPD framework [65, 67]. In 2006, laser-sintering was introduced to produce RPD frameworks digitally in order to eliminate the investing and casting steps [68]. Due to the lack of specialized software, selective laser-sintering originally required the use of a physical sculptor to virtually build the framework [69]. The physical sculptor is a haptic device that allows the users to touch and manipulate objects in a 3-dimensional (3D) virtual environment. It helps technicians to utilize hand movements very close to the hand movements they use for conventional framework wax-up, but it increases the time, cost, and complexity of the procedures [69].

To overcome these limitations, different software solutions were tested to virtually design RPDs without the need for a sculptor. However, these programs were not specifically developed for RPD design and required lengthy procedures to determine the path of insertion, eliminate undesirable undercuts, and draw the framework components [70]. Specialized software for designing RPD framework was not introduced until 2010 [71]. Surface roughness and long post-processing steps are limitations of laser-sintering technology. Recently, simultaneous technology of repeated laser-sintering with high-speed high-precision milling was introduced to fabricate RPD with higher precision and smoother surfaces [72]. This technology integrates both laser deposition and high-speed milling on the same platform. The fabrication starts with ten layers of laser deposition followed by highspeed milling to smoothen the surface and provide extra detail precision [73]. This technique proves effective for titanium RPD, which overcomes the casting challenges of

titanium [74]. Moreover, laser-sintering followed by metal annealing was also used for titanium RPD fabrication which increases the ductility and improves resistance to crack [75].

2.4.2.1 Digital RPD in today's market

Most of the available designing systems do not require physical sculptors, although the Geomatic® Touch™ X (3D systems, South Carolina, USA) still requires it. The available digital systems for producing the digital RPDs are either direct metal production systems including laser-sintering systems or indirect production including the stereolithography systems; the special variation of it is the digital light processing (DLP) and milling [14].

2.4.2.2 Clinical evidence on digital RPD

Digital RPDs are new products and therefore have not been studied thoroughly yet. Most of the studies in this field have been focused on testing the feasibility of the technique, and they have shown that digital direct or indirect metal fabrication can produce accurately fitting RPDs [66, 70]. Extraoral scanning of the master cast has been reported effective in several studies and resulted in well-fitting RPD frameworks [14, 66]. On the other hand, intraoral scanning is effective for capturing in Kennedy class III cases [76-78], but not Kennedy class I and II as the scanning does not capture the physiologic extensions of the movable mucosa [76].

Laboratory studies showed that laser-sintered cobalt-chromium alloys are about eight times more accurate than casting and have better mechanical properties, higher yield strength and fatigue resistance compared to cast Co-Cr alloys [79]. Moreover, Akers clasps produced by simultaneous repeated laser-sintering and high-speed milling showed higher fitting

accuracy and retention forces compared to conventional cast clasps [80]. However, when the fit of laser-sintered RPD frameworks was compared with lost-wax technique, milled and 3D-printed frameworks, laser-sintered frameworks demonstrated significantly larger gaps than all other techniques. Technical parameters might need to be adjusted to get better fitting results [81]. Several factors can affect the final product in laser-sintering, including heat treatment, amount of relief designed, and position and angulation of the support structure [72]. Moreover, with this new technology, time is required to get to the top of the learning curve and optimize the product [82].

2.4.2.3 Advantages of digital RPDs

Digital production of RPD has several potential advantages. Indirect fabrication techniques benefit from the digital designing step which saves time compared with manual surveying and framework wax-up. Also, direct metal fabrication systems increase productivity and shorten the work flow while reducing manufacturing costs as several steps are omitted (cast duplication, manual wax-up, investing and casting) and reduce maintenance cost for expensive investing and casting machines.

Digital production can be environmentally friendly considering the potential reduction in environmental impact due to reduced waste of alloy, wax, and investment materials (this applies to direct metal production systems) and the recycling potential of uncured metal powder left after laser-sintering.

Moreover, virtual designs can be saved for later use which enable dentists to provide patients with extra prosthesis or replacement prosthesis with the same or modified design without the need to restart the entire process. This also permits sharing designs between technicians and clinicians via internet/e-mail, which improves communication.

Digital production opens the door for endless opportunities to enhance both the work flow and the quality of provided treatment; RPD with optimized designs can be provided for individual patient to provide required mechanical properties needed in the different oral environment of each case [83, 84]; moreover digital RPD can be performed for cases requiring altered cast technique and with added simplicity and shorter steps [85]. Digital production may open the door for different materials to be used for RPDs like polymer-based materials, which can overcome some of the limitations of current metal RPD [6].

Utilizing intraoral scanning can provide greater success with gagger patients, patients with special needs, or anxious patients. It involves multiple section scanning so it is easier to control moisture section by section than to control moisture for the whole arch at one time. It uses multiple scans that are stitched together automatically at real time, so any defect or deficiency in the impression can be identified and corrected at the same visit [78].

2.4.2.4 Limitations of digital removable partial dentures

Digital fabrication of RPDs has some limitations. First, this technology only allows fabrication of the metal framework, but it does not allow for digitalized tooth setup; currently tooth setup needs to be done manually. Another limitation is the high initial cost of the machine. This technology requires time and expertise to learn the technique.

Digital RPDs currently require special supports to hold the prostheses during the 3D-printing process. This adds extra steps for planning the supports and removing them after fabrication. Another limitation is the staircase effect, which may appear due to the layering nature of the 3D-printing process. It can be significantly reduced by reducing the layer thickness which could increase the production time [86]. Moreover, currently this

technique cannot be used for all patients, since some special designs cannot be produced easily because of the limitations of the available software and manufacturing procedures.

2.5 Effectiveness of removable partial denture

Traditionally, dental restorations including removable partial dentures were evaluated by dentists against predetermined clinical measures including survival rates, risk of tooth loss, risk of periodontal damage and clinical complications [87-89]. However, these outcomes are reported by clinicians and although they are very important, they may not necessarily reflect patients acceptance.

Research has shown that dentists evaluate RPD treatments differently than patients. In a cross sectional study, only 50% of RPDs examined were considered clinically acceptable by dentists, despite that about 68% of patients were satisfied with their RPDs. Currently, using patient perception of the treatment to evaluate treatment effectiveness has gained popularity [90-92] and resulted in a major reform in oral health research [91, 93].

2.5.1 Clinical outcomes

2.5.1.1 Survival and success rates

Several studies have assessed the survival rates of clasp-retained RPDs after different follow-up times. Thomason et al reported survival rates of about 25% at 5 years [94]. In another study, treatment failure rates of 15 to 20% were reported for cobalt-chromium or titanium RPDs at 2 years [95]. Kapur et al reported RPD treatment success rates of about 25% at 5 years [96].

A recent systematic review of the clinical performance of different metal-based removable partial dentures in moderately reduced dentition concluded that the 5-year failure rate of cast removable partial dentures range between 33 and 50%, and that could be significantly reduced by a stringent follow-up program [97]. It was also proven that denture non-wear accounts for about 15-20% of treatment failure and occurred relatively early during the observational study period [97]. This review has also highlighted the inadequate reporting and the methodological flaws in the literature and recommended higher quality studies to improve the level of evidence on this topic [97].

2.5.1.2 Biological complications on the supporting tissues

It is generally believed that RPDs are usually associated with harm to the supporting teeth, bone and soft tissues [98]. However, clinical studies showed that well-made RPDs with hygienic design, and stringent pre-treatment and follow-up care can survive for as long as 25 years without negative complications in the oral cavity [99-102]. A recent systematic review on the biological complications of various types of RPDs found out that appropriate pre-treatment and supportive care can reduce the biological complications associated with RPDs [98]. However, patients are not always seen for regular follow-up after RPD treatment, and oral hygiene and denture hygiene routines are not always maintained [103].

In the absence of these measures, up to 18% tooth loss, 32.7% caries, 19.2% endodontic treatment and 5.3% tooth fracture were reported for clasp-retained RPDs. RPD abutment tooth loss has also been significantly associated with crown-root ratio, pocket probing depth, root canal treatment and abutment type [98].

2.5.1.3 Technical prosthetic complications

Loss of retention and pain are the first and second most common complaints of patients using RPDs and they are the most common reasons to look for a new denture [104, 105]. Loss of retention can be caused by residual bone resorption, abutment teeth loosening or loosening of clasps [106]. Alternatively, loss of retention can be related to poor prosthesis design, poor fabrication or ill-functioning materials [63]. Pain can be related to mucosal inflammation which is commonly seen under removable partial dentures [104, 105].

Clasp fracture and framework fracture are among the most common reasons for RPD repair, this can occur in 10-20 % of cases within 5 years of delivery and in 27-44% after ten years [107]. The rate of lower RPDs framework fracture is about double (21.1%) that of upper RPDs (10%) [48].

2.5.2 Patient-reported outcomes for removable partial denture

Subjective assessment of oral health has become a major interest in dentistry and dental research. Currently, many research studies evaluated the self-perceived oral health in diverse populations. Early contributions in this area started with modifying the concepts of health and models of diseases to include the complex multidimensions of health which includes cultural, environmental, psychological and social aspects [108]. These models provided a conceptual and theoretical rationale for the development of several indices and scales to measure self-perceived oral health, which are called patient-reported outcomes measures [108, 109].

Patient-reported outcomes are defined as any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else [110]. The main aim of patient-reported outcomes is

to complement the conventional and normative clinical measures that have been central to oral health research for most of its history [108].

Generally, there is a paucity in the literature concerning patient-reported outcomes for removable partial denture patients [9, 17]. The most common patient-reported outcomes used in removable partial denture research are patients satisfaction and oral health-related quality of life [9].

2.5.2.1 Patient satisfaction

Patient satisfaction is one of the most commonly used patient-reported outcome in prosthodontic research [111]. Patient satisfaction has been associated with the patients continuous use of their removable partial dentures [8]. Studies reported variable satisfaction scores for removable partial denture patients [3, 8, 104, 112-115]. The highest reported score was reported in a cross sectional study in Zagreb, Croatia which reported that about 91% of patients were satisfied or highly satisfied [116]. In this study, all patients had Kennedy class I partial edentulism [116]. In average, most studies reported that around 60% of patients are satisfied with removable partial denture treatments, while about one third of removable partial denture patients are dissatisfied [114, 117-119].

2.5.2.2 Oral health-related quality of life

Oral health-related quality of life is a complex concept that has many definitions. Locker et al defined OHRQoL as “the extent to which oral disorders affect functioning and psychosocial wellbeing” [120]. It was defined by the US National Institute of Dental and Craniofacial Research (NIDCR) as a multidimensional construct that reflects among other things people’s comfort when eating, sleeping, and engaging in social interaction, their

self-esteem, and their satisfaction with respect to their oral health [120, 121]. This concept currently has high significance in dental clinical practice, research and education [120, 121].

Oral health-related quality of life was used in few studies as an outcome to assess treatment effectiveness of removable partial denture patients or to compare between this treatment and other treatment alternatives. Removable partial denture treatments have been shown to significantly improve oral health-related quality of life of partially edentulous patients [122-124].

There are few systematic reviews that synthesized the evidence available in the effect of prosthetic interventions including removable partial dentures on oral health-related quality of life [9, 39, 125-127]. Among them, three systematic reviews focused on shortened dental arch cases [124, 126, 127], while two other reviews covered all cases of partial edentulism [9, 39]. These systematic reviews showed that removable partial denture treatment was associated with significant improvement in OHRQoL in cases with shortened dental arch, although their impact was not significantly different than functional treatment [124, 126, 127]. However, their conclusions were based on a small sample size and studies of overall low quality [126, 127].

In a systematic review and meta-analysis of prosthetic interventions to restore partial edentulism cases, removable partial dentures were associated with significant improvement (about 12% improvement of the score range) in oral health-related quality of life in 9 months or less follow-up studies, but no significant improvement in studies of more than 9 months follow-up. This review has indicated that most of the included studies did not adjust

neither report sufficient data regarding clinical confounders such as number and position of missing teeth, and therefore these results should be considered cautiously [39].

2.5.3 Factors influencing patient-reported outcomes of removable partial denture treatment

Several factors have shown association with patient-reported outcomes of removable partial denture treatment. These factors could be classified into three types: clinician-related, patient-related and denture-related factors.

2.5.3.1 Clinician-related factors

Clinician-related factors include clinical experience and knowledge of the clinician. In a cross sectional study, Frank et al assessed the association between patient satisfaction and the quality of mandibular distal extension removable partial denture, and found no significant relationship between them [128].

2.5.3.2 Patient-related factors

Patient-related factors that showed significant association with patients satisfaction include; patient age, general health status, previous experience with removable partial denture, type of restoration on opposing arch, Kennedy classification of edentulism, and number and location of restored teeth [4, 7, 8]. Older patients had shown significantly higher satisfaction compared to younger patients [4]. Patients with prior RPD experience had shown significantly higher satisfaction compared with patients receiving RPD for the first time [4]. Patients with RPD on the opposing arch had significantly lower satisfaction compared with patients with complete denture or natural teeth in the opposing arch [4]. Patients with RPD replacing anterior teeth had shown significantly higher satisfaction scores compared with RPDs replacing posterior teeth [113].

2.5.3.3 Denture-related factors

Denture-related factors could include denture material, fabrication technique, denture design, and artificial tooth color, shape and size [6, 8, 9]. These factors are the focus of this thesis.

2.5.4 Gap of knowledge

Currently, there are only two attempts to synthesize evidence on patients-reported outcomes for removable partial denture patients, one is a systematic review [9], and the other is a narrative literature review [17]. They identified some denture-related factors that affect patient-reported outcomes, which include color and shape of prosthetic teeth [9, 17]. However, other factors like denture base material and denture fabrication technique were not evaluated in these reviews. Kolciuk et al stated that studies assessing effects of denture base on patient-reported outcomes showed conflicting results, however, the reasons behind the conflicting results were not further explored and evidence was not synthesized on this topic [17]. This is the first gap identified in this thesis.

Although advanced digital technologies have been used recently to fabricate removable partial dentures, they have been quickly implemented in dental laboratories worldwide. Currently, there is only a handful studies on the clinical performance of removable partial dentures fabricated digitally [86, 129], and most of which are clinical case reports [65, 66, 68, 76, 130]. Two studies assessed the clinical fit of digital removable partial dentures, one produced by laser-sintering, and the other by 3D printing followed by traditional casting [86, 129]. Both showed that digital RPDs had variable fitting discrepancy but were considered clinically acceptable [86, 129]. No studies yet have evaluated the effectiveness of digital removable partial dentures utilizing patients-reported outcomes. Clinical trials

are needed to evaluate this new technology in RPD fabrication before it can be recommended. This is the second gap identified in this thesis.

Satisfaction with tooth color of artificial denture teeth has shown significant association with denture wear rate, indicating the high importance of tooth color from patients perspective [8]. Dentists are now advised to listen to their patients as the main guide for tooth color selection [24]. Literature regarding patients preferred tooth shades and factors that affect people preference of different tooth shades is scarce. Currently, there is no studies assessing people preferences of esthetic tooth shades in North America. This is the third gap identified in this thesis.

Chapter Three: Methods

3.1 Study Designs

This thesis contains three projects with three different study designs: systematic review, crossover clinical trial and cross-sectional survey study.

3.1.1 Systematic review

Evidence-based medicine is the process of integrating individual clinical expertise with the best available external clinical evidence from systematic research [131]. With the recognition of the importance of evidence-based decisions in health care, the demand for synthesizing and evaluating the available evidence in the medical literature has become increasingly important [132]. To synthesize knowledge for a particular clinical question, one must retrieve and summarize all pertinent studies in the literature, which is an overwhelming tasks for clinicians [131]. Therefore, clinicians usually turn to review articles that already synthesized the available evidence to guide their clinical decisions [131]. There are several types of review articles that synthesize knowledge from primary studies, which include narrative reviews, descriptive or mapping reviews, scoping reviews, systematic reviews, realist reviews and critical reviews [133].

A systematic review involves the application of scientific strategies to the selection, critical appraisal, and synthesis of all relevant studies that address a specific clinical question, in a way that could minimize bias. A meta-analysis is a type of systematic review that uses statistical methods to combine and summarize the results of several primary studies [134]. Systematic reviews can be used to inform medical decision making, plan future research projects, and establish clinical practice guidelines [134].

Systematic reviews are designed to answer specific narrow clinical questions in depth. To formulate the question, five main aspects should be explained (PICOT); P stands for the population with a specific condition in a specific setting, I stands for the intervention or treatment of interest, C stands for the control, O stands for the outcome/s of interest and T stands for follow-up time [134]. Systematic reviews can include different study designs such as observational studies, animal studies, in-vitro studies, however, systematic reviews of controlled clinical trials are considered the highest level of evidence for treatment effectiveness questions, according to the Oxford Center for Evidence-based Medicine levels of evidence [135], table 3.1.

Table 3.1: Oxford Center for Evidence-Based Medicine Levels of Evidence 2011 for treatment effectiveness questions

Level of evidence	Studies
1	Systematic review of randomized controlled trials or all or none trials
2	Randomized controlled trials
3	Systematic review of non-randomized controlled cohort studies Individual non-randomized controlled cohort studies/ follow-up studies
4	Case-series, case-control studies, or historically controlled studies
5	Mechanism-based reasoning

Systematic review designs have several limitations. On of this limitation is heterogeneity as in systematic reviews, results from different studies with different patients, and intervention characteristics are pooled together in a meta-analysis, which raises concerns that the pooled results might not be applicable on everyday clinical practice [136]. There are several sources of heterogeneity in the results of the systematic reviews, some related to the participants and intervention characteristics which are called clinical heterogeneity, some are related to differences in the trial designs and execution which are termed methodological heterogeneity, and variability in the summary treatment effects among trials which is called statistical heterogeneity [137]. These sources of heterogeneity are not necessarily mutually exclusive [137]. Another limitation is that the systematic review is limited by the quality of the primary studies. If a clinical question is answered by few studies of low quality, a systematic review of these studies would not be better than the quality of the primary studies. Publication bias is also a limitation of systematic reviews due to the difficulty of finding unpublished data [134].

3.1.2 Crossover clinical trial

Crossover study design is an experiment where participants are randomly assigned to a series of treatments and each participant serves as his/her own control in estimating treatment effect. In this design, the treatment effect is estimated as the average of within-participants differences [138]. One of the biggest advantages of crossover trial design is that it requires a smaller sample size compared with parallel arms study designs due to the smaller variance in within-participants readings [138].

There are several considerations that should be considered when planning and analyzing crossover trials. The first consideration is the carryover effect which means that the treatment from one period may have a residual effect that persists into the subsequent period. Therefore, a “washout period” long enough to eliminate the first intervention effect is usually recommended to minimize the carryover effect [138]. However, in some cases, there are ethical considerations that preclude a washout period, when giving no treatment is not in the participants’ best interest. To deal with the carryover effect, some researchers recommend estimating and testing for the carryover effect, and when present, then only the data in the first period is included in the analysis. On the other side, other researchers recommended using crossover trial only when the assumption that there is a minimal carryover effect is likely true, and thus carryover effect is ignored and not tested [138].

Another consideration is the period effect, which occurs when the treatment effect is not constant over time, especially when the treatment periods are long, or the underlying condition is not stable. Additionally, dropouts and missing data in this design have larger impact than in parallel arms studies [138]. Thus, crossover trial study design is not appropriate when the treatment to be tested has a permanent effect that could alter the course of the disease or condition [138].

3.1.3 Cross-sectional study design

The cross-sectional study is an observational study design where data are collected at one time point only. Cross-sectional studies are usually used to measure prevalence (the number of cases in a population at a given point of time), and sometimes used to infer causation [139]. The main advantages of this study design is being simple, quick and inexpensive. Additionally, data on multiple outcomes is collected at one time point, and

seldom ethical difficulties are faced in this design [139]. However, a main limitation is that cross sectional studies can identify simple associations, but cannot explain cause and effect relationships.

Two main considerations are important in cross sectional study designs; the sampling technique and the response rate. A well representative sample should be drawn from a representative population randomly, which might require time, efforts and expenses. Adequate measures should be taken to ensure a high response rate, as low response rate could negatively affect the validity of the study [139].

3.2 Measurement tools

In this thesis, two main measurement tools were used, which are McGill Denture Satisfaction Questionnaire and Oral Health Impact Profile OHIP.

3.2.1 McGill Denture Satisfaction Questionnaire

McGill Denture Satisfaction Instrument, is a validated survey that was used in several studies in conventional and implant-supported complete dentures to measure patients satisfaction [93, 140, 141]. This instrument measures patients satisfaction in relation to 9 items: ease of cleaning, ability to speak, comfort, esthetics, stability, ability to masticate several types of food, masticatory efficiency, oral condition, and general satisfaction. Visual analog scale (VAS) was used to score the items in McGill Denture Satisfaction Instrument, which is a continuous scale comprised of a horizontal line usually 10 cm long and anchored at both ends by verbal descriptors [142]. In McGill Denture Satisfaction instrument, the VAS is anchored with totally unsatisfied at one end and highly satisfied at

the other end [90]. VAS is more sensitive than categorical Likert-scale in detecting small differences in patients' satisfaction between different restorations [90].

To develop this instrument, researchers asked a group of edentulous patients to write down what aspects of their dentures were important to them [90]. By doing that, they included items that are important to patients, thus provided a very sensitive instrument to measure patients satisfaction. Denture-related items included in this instrument; esthetics, speech, chewing ability, ability to clean, stability and comfort showed significant association with patients general satisfaction of their dentures and explained 89% of the variation in the general satisfaction [141]. The construct and content validity of this questionnaire has been demonstrated [140].

Currently, there is no sensitive instrument validated to measure patient satisfaction in removable partial denture research, however, being a removable denture, the partial shares common points with the complete and therefore it is expected that the McGill instrument could work equally well in removable partial denture research. In fact, the McGill instrument has been used for a wide range of dentures including implant-supported overdentures [143, 144].

3.2.2 Oral Health Impact Profile

The oral health impact profile (OHIP) was developed to capture a variety of impacts (including oral functional effects, pain and personal effect as well as social interaction) of oral conditions among individuals [145]. For the development of OHIP, Locker's model of oral health was used to identify conceptual domains in the hierarchy of social impact. In this model, disease can lead to impairment which is anatomical loss, which can then lead to functional limitation, discomfort or impairment [145]. Following this model, OHIP has

seven domains of impacts, which are functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap [145]. The reliability, construct and content validity of OHIP was demonstrated in previous studies [109]. OHIP could be used in epidemiological surveys to demonstrate the impact of oral conditions on the population quality of life. It could be used also to evaluate and effectiveness of different treatments in clinical trials [108].

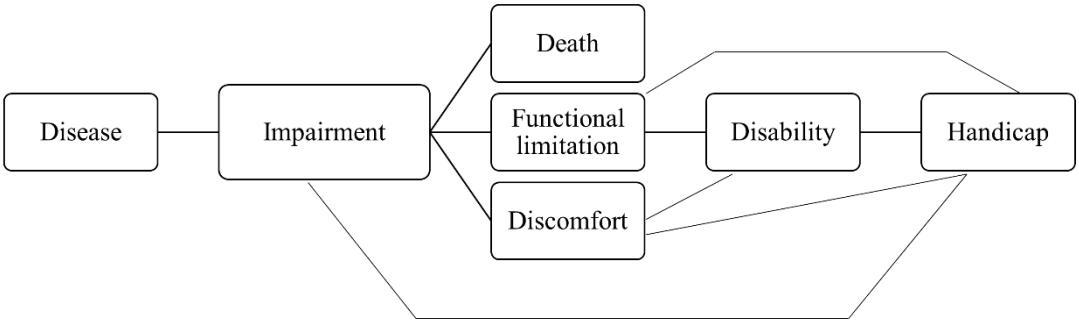

Figure 3.1: Locker's conceptual model of oral health adapted from Slade and Spencer, 1994 (145)

The OHIP questionnaire consists of 49 questions, in which participants are asked to indicate how frequently they experience a problem on a five points Likert scale from "very often" to "Never". A shortened version of OHIP, OHIP-14, was recently introduced. It contains 14 questions conceptually divided into the same seven domains of the original OHIP [2, 145].

The results of OHIP questions could be presented in terms of the overall scores and specific domain scores. One of the ways to compute the overall OHIP score is by simple addition. For each item in the OHIP questionnaire, the 5 frequency responses are scored as the following: "never" (score 0), "hardly ever" (score 1), "occasionally" (score 2), "fairly

often" (score 3), and "very often" (score 4) [2]. The overall score of OHIP-14 could range from 0-56. Higher overall score indicates greater impairment in oral health-related quality of life [2].

3.3 Statistical models

Mixed effects regression models are extension of the simple regression models to allow for both fixed and random effects. In simple regression models, there is one source of variability which is the random sample we used for the study, but in mixed effects models different sources of variabilities are considered in the analysis by including random effects [146]. In this thesis, mixed effects models were used to analyze the data in two projects; the crossover clinical study and the cross sectional study. Mixed effects models can also be called models of repeated measurements or hierarchical models. They are used to analyze complex clustered data or longitudinal data and to analyze data with multiple sources of variation [146].

Clustered data arise from designs where the units of analysis are nested within clusters, for example collecting data from students nested within different classrooms [147]. In these designs, observations between clusters are independent but observations within clusters are dependent because they belong to the same subpopulation. Mixed models account for the correlation between participants readings clustered in the same group [146].

Longitudinal data arise from designs where repeated measurements are collected from the same participants over time [147]. Measurements collected from the same participants are

likely to be correlated. Mixed models involve estimation of covariance parameters to capture the nature of this correlation [147].

Another advantage of mixed models is their ability to model fixed and random effects. Fixed effects are represented by unknown constant parameters in the model. The estimation of these parameters is generally of intrinsic interest to the researcher, because they indicate the relationship between the covariates and the outcome. Random effect on the other side are modeled as unobserved random variables when the estimation of these variables is not of intrinsic interest to the research question. Random effects allow researchers to account for random variations that could occur due to differences in some variables [147].

Chapter Four

Patient-reported outcomes of metal and acrylic resin removable partial dentures: a systematic review and meta-analysis

Patient-reported outcomes of metal and acrylic resin removable partial dentures: a systematic review and meta-analysis

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4.1 Abstract

Purpose: Metal removable partial dentures (RPDs) are often considered long term treatment options for partially edentulous patients, while acrylic resin RPDs are considered interim treatments. The aim of this review was to compare metal and acrylic resin RPDs regarding patient-reported outcomes for partially edentulous individuals.

Materials and Methods: Four databases (MEDLINE, EMBASE, CENTRAL, Web of Science) were systematically searched for observational studies and randomized controlled trials comparing patient-reported outcomes between metal and acrylic resin RPDs. The primary outcome was patient satisfaction. Included studies were assessed for risk of bias using the Cochrane risk of bias in non-randomized studies of interventions tool (ROBINS-I) and the Cochrane Collaboration Risk of Bias Tool for Randomized Controlled Trials. The level of evidence was evaluated using Oxford Center for Evidence-based Medicine tool. A random-effects model was used to analyze the data.

Results: A total of 15 studies were included in the systematic review; 10 in the meta-analysis. The pooled effect size for patient satisfaction and oral health-related quality of life showed no statistical significant difference between metal and acrylic resin dentures (0.22, 95% confidence interval -0.01, 0.45, p=0.06; 1.45, 95% confidence interval -2.43, 5.33, p=0.46, respectively). Noncompliance with using removable partial dentures was significantly lower in patients with metal compared to patients with acrylic resin dentures (pooled odds ratio=0.57, 95% confidence interval 0.45, 0.73, p<0.001). Most studies had critical to serious risk of bias and low level of evidence.

Conclusions: The reviewed studies showed that there was no significant difference between metal and acrylic resin removable partial dentures in patient satisfaction and oral

health-related quality of life. Metal dentures were associated with higher patient compliance rates and were preferred more by patients compared to acrylic resin dentures. However, the reviewed studies had low levels of evidence and therefore, high quality randomized controlled trials are needed to conclusively address the question of this review.

Keywords: Oral health-related quality of life, patient satisfaction, partially edentulous, denture bases

4.2 Introduction

Despite the declining rate of tooth loss [1] and the increased demand for implant restorations in developed countries [2], removable partial dentures (RPDs) remain a widely used treatment option to restore function in partially edentulous patients [3, 4].

In the current practice, metal RPDs are used as a long term treatment option and acrylic resin RPDs as an interim treatment option [5]. Interim dentures are usually indicated as a part of the overall treatment plan to maintain space, condition teeth or residual ridges, re-establish occlusal relationship, and restore function and esthetics during the course of treatment [6, 7]. Metal dentures are usually designed carefully following specific biomechanical considerations to achieve optimum retention, stability, and support in order to minimize damage to surrounding structures [7, 8]. Acrylic resin dentures are designed to be mucosal-borne, which is thought to violate the biomechanical considerations of RPD design and is believed to be injurious for the adjacent structures if such dentures are used for long term [5, 7].

Clinical survey studies show that acrylic resin RPDs are used frequently and for long periods [9, 10]. In fact, they comprise around 33 to 75% of RPDs provided to patients in different countries [9-11]. In some countries, only acrylic resin RPDs are covered by governmental health insurance, so this is the only accessible restoration for patients of lower socioeconomic status [12, 13].

Recently, using patient-reported outcomes such as quality of life and patient satisfaction to evaluate treatment effectiveness of therapeutic interventions, including prosthodontic interventions, has gained popularity [14-21]. In the field of removable partial dentures, there is a paucity in the literature concerning the patient-reported outcomes [22]. Previous

attempts to synthesize evidence in these outcomes, included only metal RPDs [22-27]. They identified factors that affect patient-reported outcomes which include patients age, previous prosthesis experience, type of edentulism including location, number and symmetry of missing teeth and color and shape of prosthetic teeth [22]. However, the effect of denture base was not evaluated in these publications [28]. This supports the need to synthesize the available knowledge on patient-reported outcomes for patients wearing metal and acrylic resin RPDs, which could help update current clinical guidelines.

Therefore, the objective of this systematic review was to answer the following question: "is there any difference in patient-reported outcomes in partially edentulous individuals wearing metal or acrylic resin RPDs?"

4.3 **Materials and methods**

This systematic review was registered in (Prospero #CRD42018109807) (http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018109807) and was reported following PRISMA guidelines [29, 30].

4.3.1 Search strategy

A systematic search strategy, developed with the help of a medical librarian trained in systematic review searching, was created for the MEDLINE OVID database then adapted for EMBASE, CENTRAL Cochrane Central Register of Controlled Trials, and Web of Science (Table 4.1). The search strategy included Medical Subject Heading (MeSH) terms or their equivalent where available, and keywords for the population and interventions. All databases were searched from inception to October 4, 2016; the searches were then updated

on May 4, 2018. No language restrictions were applied. A hand search was conducted by manually checking relevant references of included articles, and relevant reviews.

Table 4.1: Systematic review search strategy in MEDLINE

Search date	**October 4/2016, updated May 4/2018**
Population	#1—(Jaw, Edentulous, Partially [MeSH]) OR (partial* adj5 (dentition* or dentate* or edentul*)) OR (Dental Clasps [MeSH]) OR (Denture, Partial, Removable [MeSH]) OR (removabl* adj3 partial* adj5 (denture* or dent* or prosth*)) OR (RPD) OR ((kennedy or aramany) adj1 class*)
Intervention	#2—(Methacrylates [MeSH]) OR (Methylmethacrylate [MeSH]) OR (Acrylic Resins [MeSH]) OR (Resins, Synthetic [MeSH]) OR (acrylic* or acrylate*) OR (MMA or PMMA) OR (Denture Bases [MeSH]) OR (Denture Design [MeSH]) OR (Denture Bases [MeSH])
Comparison	#3—(Dental Alloys [MeSH]) OR (Vitallium [MeSH]) OR (metal* or alloy*) OR (cobalt or chrome or chromium or titanium or molybdenum) OR (vital?ium)
Outcome	Not included
Filters	None
Final Search	#1 AND (#2 OR #3)

4.3.2 Eligibility criteria

For inclusion in the review, a study must have reported outcome data for both types of RPDs, metal and acrylic resin. All studies in any language were included in this review if they have had an English abstract. Only conventional clasp-retained cast metal RPDs made of cobalt-chromium alloys were included. Implant-supported, telescopic crown-retained, or removable partial overdentures were excluded as these designs are more expensive, more complicated, and not widely used in treating partially edentulous patients [31]. Only mucosal-borne (tissue-supported) acrylic resin RPDs with or without wrought metal clasps were included. Acrylic resin RPDs made with metal reinforcement in terms of bars, cast clasps, or rests were excluded. Unilateral RPD designs were also excluded because of contraindication of use and the inherent risk of aspiration [32].

The primary outcome for this review was patient satisfaction. The secondary outcomes included oral health-related quality of life, patient compliance rates with RPD treatment and RPD preference. In this review, the level of patient compliance with removable partial dentures was related to use of the dentures occasionally or discarding the dentures. Considering the expected low number of randomized clinical trials, observational studies were included in this review. Case reports, case series, expert opinions, commentaries, editorials, reviews, and conference abstracts were excluded.

4.3.3 Studies selection

Three reviewers (BA, AA, RR) screened abstract and full-text of potentially relevant articles independently. Disagreement between them was resolved by consensus.

4.3.4 Data extraction and risk of bias assessment

Data extraction and risk of bias assessment were conducted independently by 2 co-authors (BA, RR) and disagreement was resolved by consensus. The data included: patient characteristics (age, sex, previous RPD experience, Kennedy classification of edentulism, number and location of missing teeth, oral and RPD hygiene habits, opposing arch status), prosthesis-related characteristics (RPD design, RPD age, RPD use), study characteristics (study location, year of publication, study design, target population, sampling strategy, study setting, sample size, follow-up time, response rate or drop-out rate and characteristics of non-respondents), type of measurement instruments and outcome data. Corresponding authors of eligible studies were contacted via emails for missing information or for clarification of reported data when necessary.

The Cochrane Risk of Bias Assessment Tool for Randomized Controlled Trials [33] and the Cochrane Risk of Bias in Non-randomized Studies of Interventions Tool (ROBINS-I) [34] were used to assess the risk of bias for randomized controlled trials and observational studies, respectively.

The ROBINS-I tool includes 7 domains: bias due to confounding, selection of participants, classification of intervention, deviation from intended intervention, missing data, measurement of outcomes, and selection of the reported results [34]. For the bias due to confounding domain, the following potential confounders were examined: RPD age, number of restored anterior and posterior teeth, Kennedy classification of partial edentulism, status of opposing arch, previous RPD experience, patient age and sex, and RPD quality [22, 35, 36]. The level of evidence was evaluated using the Oxford Center for Evidence-based Medicine [37].

4.3.5 Data analysis

Standardized mean difference (SMD), mean difference and odds ratio were used to compare acrylic resin and metal RPDs on patient satisfaction, OHRQoL, and patient compliance, respectively. Inverse-variance statistical method in a random effects model was used to account for interstudy variations.[38]

Heterogeneity among the pooled studies was tested using Cochran *Q* test and I^2 statistic. I^2 statistic of more than 50% was considered an indicator of heterogeneity of outcomes. A $p < 0.05$ was considered significant.

Funnel plots of studies included in the meta-analysis were used to assess potential publication bias. Tests of funnel plots asymmetry were not performed as less than 10 studies were included in the meta-analysis. All analyses were conducted using Review Manager 5.3 software (Cochrane Collaboration, Copenhagen, Denmark).

4.4. Results

4.4.1 Search results

The electronic search yielded 4,056 citations. After the removal of 670 duplicates, and excluding non-eligible articles, 119 articles were retained for full text screening. Out of these articles, 15 studies were included in the systematic review and 10 in the meta-analysis (Fig 4.1).

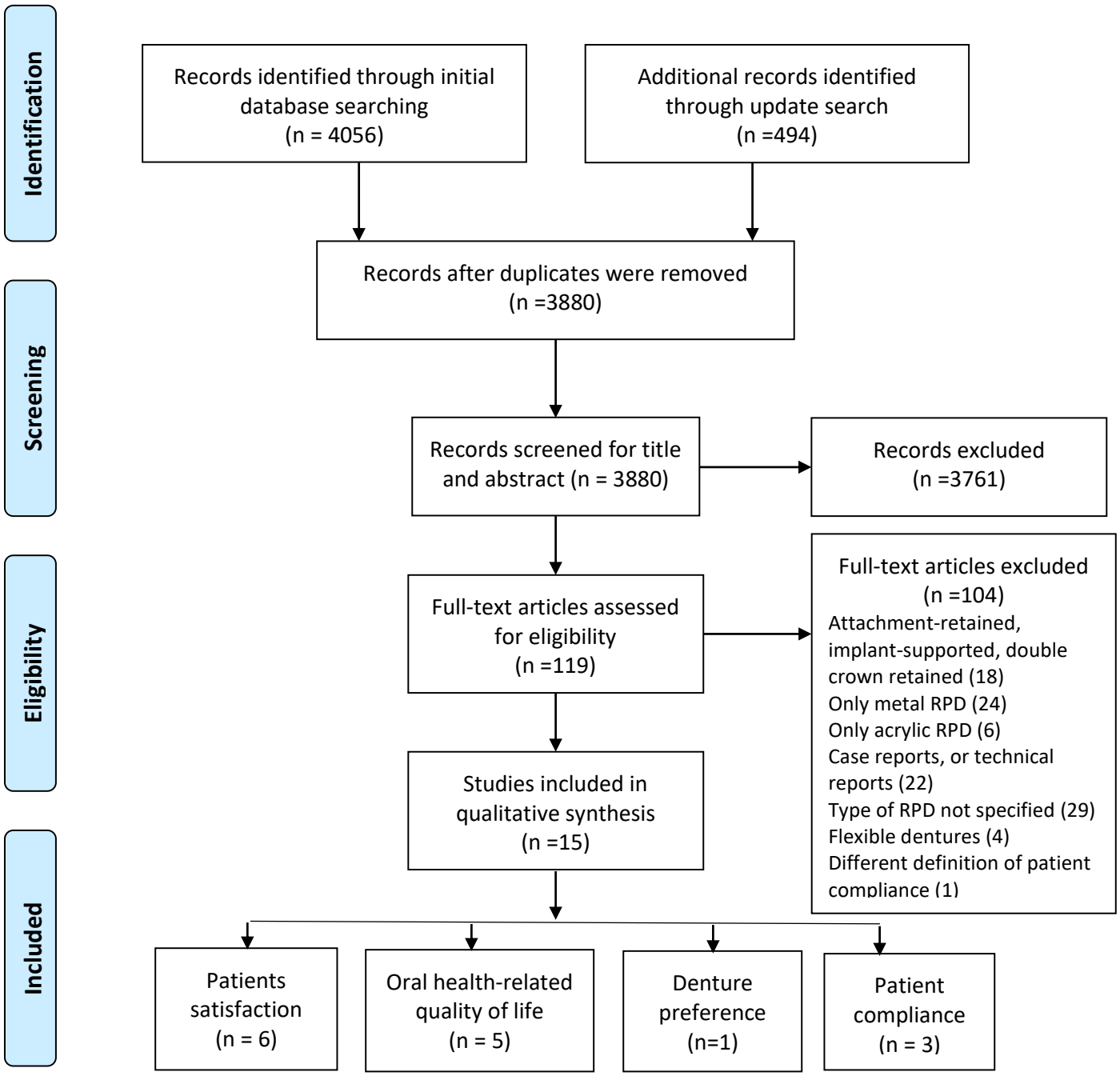


Figure 4.1: PRISMA flow chart of studies selection

4.4.2 Patients and study characteristics

All studies were cross-sectional except 2 studies, one was a randomized trial [39], and the other was cohort study [40] (Table 4.2). The earliest study was published in 1968 [41] and the most recent in 2018 [11]. The follow-up period was 21 days for the clinical trial with 0% drop-outs [39] and 1 month for the cohort study with 6% drop-out [40]. Most of the cross-sectional studies evaluated dentures that were worn for a period of 1-5 years [11, 36, 41-48]. Response rate in these studies ranged from 31.4% [42] to 90% [43].

Populations in most of the studies were patients treated in dental schools except 3 studies: 2 studies recruited patients from public hospitals [42, 49], and 1 recruited a random sample of old noninstitutionalized individuals living in Zwolle, the Netherland using the city registration system [12]. Most of the studies were published in English, except 2 studies, which were published in Japanese [41, 45]. All included Japanese publications had data only on patient compliance rates with RPD treatment [41, 45].

A total of 6 studies assessed patient satisfaction [12, 46-50], 5 studies assessed oral health-related quality of life [11, 36, 40, 42, 44], 3 studies evaluated patient compliance rates [41, 43, 45], and 1 study reported patients' preference of RPD (Fig 4.1) [39]. In 3 studies only, the primary outcome was the comparison between acrylic resin and metal RPDs on patient-reported outcomes [39, 40, 49]. Other studies included data as a consecutive cohort [11, 12, 36, 41-48, 50].

Table 4.2: Summary of included studies in the systematic review

First author, location, date of study	Study design	Recalled sample (n) Dentures/ Patients	Response rate%	Age mean± SD (range) years	Female %	Outcome	Time since denture delivery (years)
Watson et al, UK, 1986	Cross sectional	NR/53 M=56/43 A=15/10	58%	53.8 (17-79)	38%	Patient satisfaction	1-3
Van Waas et al, Netherland, 1994	"	168/123 M=71/47 A=97/76	74%	(55-74)	NR	"	NR
Wakabayashi et al, Japan, 1998	"	94/66 M=46/NR A=48/NR	NR	61.2 (42-74)	63%	"	"
Zlataric et al, Croatia, 2000	"	243/165 M=143/NR A=100/NR	"	(38-87)	64%	"	0.5-5
Zlataric et al, Croatia, 2003	"	261/205 M=154/NR A=107/NR	"	(38-89)	61%	"	NR
Aljabri et al, Saudi Arabia, 2017	"	NR/60 M=NR/20 A=NR/20	60%	51.18 ±13.06 (23-73)	50%	"	< 1
Montero et al, Spain, 2013	Prospective Cohort	NR/78 M=NR/58 A=NR/20	6%*	64±10	48%	OHRQoL	1 month
Shaghaghian et al, Iran, 2015	Cross sectional	284/200 M=NR/110 A=NR/67 A+M=28/14	79%	55% ≥50	61%	"	<1: 54.8% >1: 45.2%
Abuzar et al, Australia, 2012	"	211/232 M=NR/97 A=NR/132**	31.4%	78% >60	45%	"	<2: 38.8% 2-10:31% >10: 30.2%
Wahbi and Elamin, Sudan, 2018	"	567/370 M=NR/18 A=NR/352	NR	(35-60)	73.2%	"	<0.5: 38.9% 0.5-1: 45.1% >1: 15.9%
Ali, UK, 2017	"	91/84 M=54/54 A=23/23 A+M=7/7	70%	65.8 ±13.4	44%	"	2 months-1
Akeel, Saudi Arabia, 2010	"	75/47 M=50/NR A=25/NR	90%	47 (30-69)	0%	Patient compliance	1
Sawada et al, Japan, 2003	"	158/158 M=27/27 A=131/131	61.2%	56.2 ±10.1	83.5%	"	5
Amemori et al, Japan, 1968	"	1168/1056 M=574/NR A=594/NR	NR	NR	NR	"	0.5-5

Abbreviations: A: acrylic resin RPD, M: metal RPD, NR: not reported, SD: standard deviation, OHRQoL: oral health-related quality of life.
*Drop-out, **This group represents people who have acrylic resin denture only or one acrylic resin and one metal denture

4.4.3 Risk of bias assessment

The randomized clinical trial included in this review had a low risk of bias in all domains except allocation concealment, which was unclear, and blinding of participants, care providers, and outcome assessors, which was high risk as the nature of the intervention makes it difficult for blinding [35]. All the included observational studies had critical to serious risk of bias (Table 4.3).

Sampling strategies and target population, comparability of respondents to non-respondents, and data regarding potential confounders in the intervention and comparison groups were not adequately reported in the studies (Table S4.3, S4.4 and S4.5). The main source of bias due to confounding identified in these studies were confounding by indication, as following the clinical guidelines, patients received acrylic resin dentures as interim dentures in less favorable clinical cases or for economic reasons [12, 36, 40, 48], and not using appropriate statistical models to adjust for confounding variables. Domains that were deemed to be of low to moderate risk of bias included classification of intervention and selective outcome reporting.

4.4.4 Level of evidence in included studies

Regarding level of evidence, the majority of included studies had a low level of evidence (level 4) based on the Oxford Center for Evidence-based Medicine tool [11, 12, 36, 40-50]. Only one study had a higher level of evidence (level 2) [39], (Table S4.6).

Table 4.3: Risk of bias assessment of observational studies using ROBINS-I

Studies	Bias due to Confounding	Selection of participants	Classification of intervention	Deviation from intended intervention	Missing data	Measurement of outcomes	Selection of the reported results
Patient satisfaction							
Wakabayashi	Serious	NI	Moderate	NA	NI	Critical	Low
Watson	Serious	NI	Moderate	NA	NI	Critical	Low
Zlataric, 2000	Serious	NI	Moderate	NA	NI	Critical	Low
Zlataric, 2003	Serious	NI	Moderate	NA	NI	Critical	Low
Van Waas	Serious	Moderate	Moderate	NA	Serious	Critical	Low
Aljabri	Critical	Critical	Low	NA	NI	Critical	Low
Oral health-related quality of life							
Abuzar	Critical	Serious	Serious	NA	NI	Moderate	Low
Shaghaghian	Serious	Serious	Low	NA	NI	Low	Low
Montero	Serious	Low	Low	Moderate	NI	Low	Low
Ali	Critical	NI	Low	NA	NI	Low	Low
Elwahibi and Elamin	Critical	Low	Low	NA	NI	Low	Low
Denture wear							
Akeel	Critical	Low	Low	NA	Low	Low	Low
Sawada	Critical*	Critical	Low	NA	Critical	Low	Low
Amemori	NI	Low	Low	NA	Critical	Moderate	Low

Abbreviations: NI: no information, NA: not applicable

4.4.5 Patient Satisfaction

All 6 studies that evaluated patient satisfaction were cross-sectional studies. Satisfaction was measured using Likert scale [12, 47-49], dichotomous scale [46], or visual analog scale [50] (Table 4.2). Although these studies showed that there was no significant difference between acrylic resin and metal RPDs in patient satisfaction [12, 46-50], patients using the metal RPD were more satisfied than those using acrylic resin RPDs (Table 4.4 and S4.7), [12, 46, 49, 50].

Table 4.4: Results of included studies

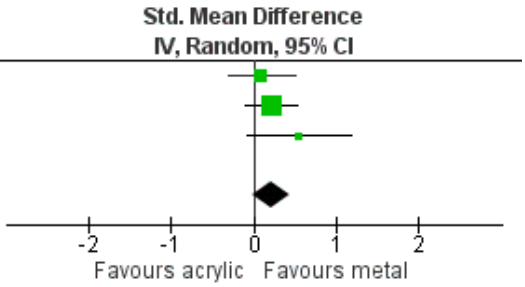
Study	Results
Watson et al, 1986	Higher proportions of metal denture wearers were satisfied (71.4%) compared to acrylic denture wearers (60%), but this was not statistically significant ($p > 0.05$)
Van Waas et al, 1994	Metal RPD wearers scored (10.3±4.2) higher satisfaction than acrylic wearers (9.4±4.2) but this was not statistically significant ($p > 0.05$)
Wakabayashi et al, 1998	Metal denture wearers scored higher satisfaction than acrylic resin denture wearers but this was not statistically significant ($p > 0.05$)
Zlataric et al, 2000	No statistical significant difference in patient satisfaction between metal and acrylic resin denture wearers ($p > 0.05$)
Zlataric et al, 2003	No statistical significant difference in patient satisfaction between metal and acrylic resin denture wearers ($p > 0.05$)
Aljabri et al, 2017	Metal RPD wearers scored higher satisfaction (3.45) than acrylic resin wearers (2.88), but this was not statistically significant ($p > 0.05$)
Montero et al, 2013	No significant difference between metal and acrylic resin RPDs in post-treatment OHRQoL scores after one month denture wear
Shaghaghian et al, 2015	Acrylic resin RPD scored significantly better OHRQoL compared to metal RPD ($p=0.03$)
Abuzar et al, 2012	Metal RPD wearers scored better OHRQoL than acrylic resin RPD, but this was not statistically significant ($p=0.388$)
Wahbi and Elamin, 2018	Acrylic resin RPD had significantly better OHRQoL compared to metal RPD wearers ($p=0.001$)
Ali et al, 2017	Metal RPD wearers scored better OHRQoL than acrylic resin RPD wearers, but this was not statistically significant ($p=0.15$)
Sawada et al, 2003	Metal denture was associated with lower odds of patient noncompliance compared to acrylic resin dentures (OR= 0.36; 95% CI: 0.13, 1.00; p= 0.050), but this was statistically not significant
Amemori et al, 1968	Metal dentures were significantly associated with lower odds of patient noncompliance (OR= 0.58; 95% CI: 0.45, 0.75; $p <0.001$)
Akeel, 2010	Metal denture was associated with lower odds of patient noncompliance compared to acrylic resin dentures (OR=0.76; 95% CI: 0.28, 2.11), but this was statistically not significant (P= 0.514)

Three studies had missing outcome data, authors were contacted but only 1 responded [49], and therefore the other 2 studies were excluded from the meta-analysis [47, 48]. The pooled SMD was 0.22 (z=1.88, 95% CI: -0.01, 0.45, p =0.06) in favor of metal RPD, however this difference was not statistically significant. No statistical heterogeneity was found (I^2 = 0%, x^2= 1.45, df = 2, p = 0.49), (Fig 4.2, A).

(A) Patient Satisfaction

Study or Subgroup	Metal Denture Mean	SD	Total	Acrylic Denture Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Wakabayashi, 1998	-43.3	51.2	46	-47.6	41.4	48	31.8%	0.09 [-0.31, 0.50]
Van Waas, 1994	10.3	4.2	71	9.4	4.2	97	55.2%	0.21 [-0.09, 0.52]
Aljabri 2017	3.45	1.12	20	2.88	0.89	20	13.0%	0.55 [-0.08, 1.19]
Total (95% CI)			**137**			**165**	**100.0%**	**0.22 [-0.01, 0.45]**

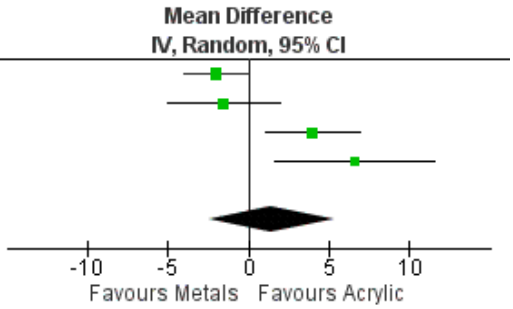
Heterogeneity: Tau² = 0.00; Chi² = 1.45, df = 2 (P = 0.49); I² = 0%
Test for overall effect: Z = 1.88 (P = 0.06)



(B) Oral Health-related Quality of Life

Study or Subgroup	Metal Denture Mean	SD	Total	Acrylic Denture Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Montero 2013	-3.9	4.1	58	-1.9	3.9	20	28.5%	-2.00 [-4.01, 0.01]
Abuzar 2012	13.82	13.03	97	15.37	13.5	132	24.7%	-1.55 [-5.02, 1.92]
Shaghghian 2015	15.5	10.5	110	11.5	9.4	76	26.3%	4.00 [1.12, 6.88]
Wahbi and Elamin 2018	17.2	10.6	18	10.6	7.5	352	20.5%	6.60 [1.64, 11.56]
Total (95% CI)			**283**			**580**	**100.0%**	**1.45 [-2.43, 5.33]**

Heterogeneity: Tau² = 12.72; Chi² = 18.65, df = 3 (P = 0.0003); I² = 84%
Test for overall effect: Z = 0.73 (P = 0.46)



(C) Patient Compliance

Study or Subgroup	Metal Denture Events	Total	Acrylic Denture Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Sawada 2003	5	27	51	131	5.7%	0.36 [0.13, 1.00]
Amemori 1968	125	574	193	594	88.4%	0.58 [0.45, 0.75]
Akeel 2010	15	50	9	25	5.9%	0.76 [0.28, 2.11]
Total (95% CI)		**651**		**750**	**100.0%**	**0.57 [0.45, 0.73]**
Total events	145		253			

Heterogeneity: Tau² = 0.00; Chi² = 1.12, df = 2 (P = 0.57); I² = 0%
Test for overall effect: Z = 4.44 (P < 0.00001)

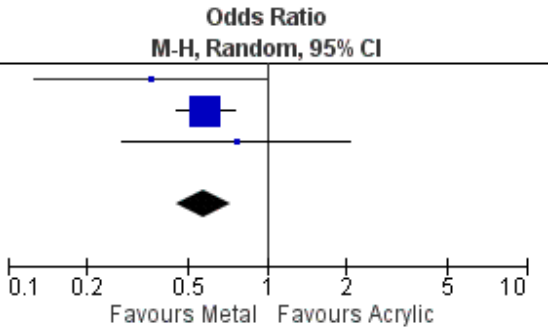


Figure 4.2: Meta-analysis of eligible studies comparing metal and acrylic resin removable partial dentures: (A) Patient satisfaction, (B) Oral health-related quality of life, (C) Patient compliance, events refer to noncompliance and odds ratio refer to noncompliance in metal over acrylic resin dentures

4.4.6 Oral health-related quality of life

The results of studies assessing OHRQoL are presented in Table 4.4 and S4.8. All included studies in OHRQoL outcome were cross-sectional [11, 36, 40, 44] except the study conducted by Montero et al., 2013 which was a cohort study with 1 month follow-up [40]. These studies used the validated Oral Health Impact Profile (OHIP) to assess OHRQoL, either in the short (OHIP-14) [11, 36, 40, 42], or the longer (OHIP-20) format [44].

Only studies that used OHIP-14 were included in the meta-analysis (n=4) [11, 36, 40, 42]. The pooled mean difference for studies on OHRQoL was 1.45 (z=0.73; 95% CI: -2.43, 5.33; p =0.46), in favor of the acrylic resin RPD patients, but this was statistically not significant. Statistical heterogeneity was I^2 = 84% (x^2= 18.65, df = 3, p = 0.0003), (Fig 4.2, B).

4.4.7 Patient compliance with RPD treatment

Patient compliance with RPD treatment was assessed in 3 studies with cross-sectional design [41, 43, 45] (Table 4.2). In these studies, the RPD was considered unused when it was discarded, or it was used occasionally. To record patient compliance with RPD, 1 study used telephone interviews [43] and the other 2 studies used mailed questionnaires [41, 45]. One study evaluated RPD use 1 year after RPD delivery [43] and the other 2 studies after 5 years (Table S4.9), [41, 45].

The percentage of unused RPDs after 5 years ranged from 32% [41] to 42% [43] for the acrylic resin patients, and from 18.2% [45] to 30% [43] for the metal RPD patients (Table 4.4). The overall pooled odds ratio of RPD noncompliance was 0.57 (95% CI: 0.45, 0.73,

p <0.0001), and in favor of metal RPDs. Statistical heterogeneity was not found (I^2 = 0%, x^2= 1.12, df= 2, p =0.18), (Fig 4.2, C).

The main reasons for RPD noncompliance regardless of RPD's type was mainly pain, discomfort [43, 45], and defects in the abutment teeth including carious lesions, periodontal diseases, or tooth loss [41]. Reasons for denture non-wear for metal versus acrylic resin dentures were not reported. Amemori et al. found that pain and discomfort were the main reason for short-term discarding of RPDs, but problems with abutment teeth or RPD fracture were the main cause of discarding dentures in long-term [41].

4.4.8 Denture preference

Only 1 study assessed prosthesis preference and it was a crossover randomized trial [39]. Age range of patients (n=15) was 18–60 years and 60% of patients were female. The study found that 14 of 15 patients (93.3%) preferred the metal RPD with bar major connector. No one preferred the metal RPD with plate major connector. This preference was explained in the study by the fact that 53% of patients (8/15) perceived that acrylic resin RPD interfered with speaking [39]. The follow-up time of this study was 5 days for each RPD followed by an additional 6 days for the preferred RPD.

4.4.9 Publication bias

To assess publication bias, Funnel plots were constructed. Funnel plots were visually slightly asymmetrical (Fig 4.3), indicating the possibility of publication bias or a systematic difference between smaller and larger studies "small study effect".

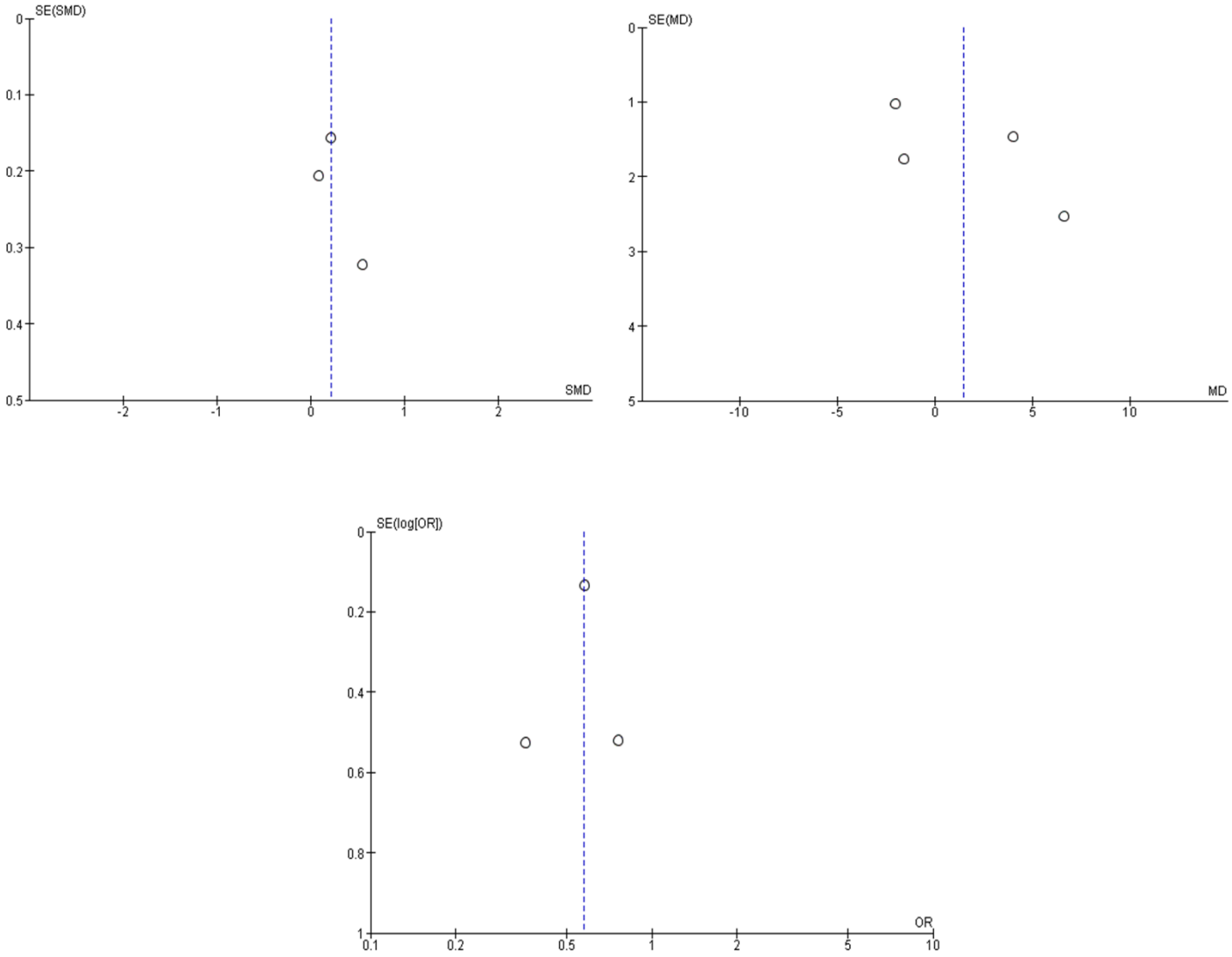


Figure 4.3: Funnel plots of the studies included in the meta-analysis: Patient satisfaction (top left), Oral health-related quality of life (top right), Patient compliance (bottom)

Abbreviations: SMD: standardized mean difference, SE(SMD): standard error of the standardized mean difference, MD: mean difference, OR: odds ratio

4.5 Discussion

Although metal and acrylic resin RPDs have been extensively used in dentistry for a long time, few studies have been conducted to compare these 2 types of RPDs on patient-reported outcomes [39, 40, 49]. This could be related to the fact that while patient-reported outcome research has gained popularity in oral health research, the interest in removable prosthodontics research has been decreasing for the past 2 decades [17, 18, 20, 51]. To the best of our knowledge, this is the first systematic review to compare the difference between metal and acrylic resin RPDs in terms of patient-reported outcomes. The reviewed studies showed that the effect of the type of RPDs on patient-reported outcomes was inconsistent. Although the pooled estimate showed no statistically significant difference in patient satisfaction and oral health-related quality of life, patients with metal prostheses had statistically significant higher compliance rates [39, 41, 43, 45]. However, these studies had several major methodological issues and their conclusions should be taken cautiously.

Regarding patient satisfaction, included studies used satisfaction scales that had not been validated, and therefore the minimum important difference is unclear, making the clinical significance of these results difficult to interpret. All included studies showed that metal RPD wearers scored higher than acrylic resin RPD wearers, however differences were not significant. Nonetheless, we must keep in mind that these statistical results might have been influenced by study design issues such as inadequate statistical power and confounding by indication [12, 46-50]. Further well-designed studies are needed to evaluate this outcome.

The pooled effect size of OHRQoL favors acrylic resin dentures but it was not statistically significant, and the effect size was (1.45, 95% CI: –2.34 to 5.33), indicates inconclusive

clinical effect when compared with the minimally important difference [52]. A previous study showed that while OHIP change scores are highly correlated with most aspects of patient satisfaction with prostheses, only satisfaction with chewing ability and oral condition were the best predictors of OHIP change scores [21]. Further well-designed studies are needed in this topic.

One drawback of RPD treatment is the high rate of noncompliance [36, 43]. Within the limits of our knowledge, this is the first systematic review in the field of removable dentures assessing patient compliance with RPD [15]. In the literature, about 19–36% of patients had discarded or occasionally used their metal RPDs [36, 43], a range similar to what was identified for the metal dentures in the studies included of this review [41, 43, 45]. The pooled estimate in this review indicated that metal RPDs were significantly associated with higher compliance compared to acrylic resin RPDs. However, as none of these studies explained the indications for metal and acrylic resin RPDs and they all have cross-sectional design, it is expected that in all these studies acrylic resin RPDs were provided to patients as interim prostheses for less favorable clinical cases following the current clinical practice [5], which could bias the conclusion. Randomized controlled trials are recommended to explore the real effect of RPD on patient compliance.

Only one crossover trial evaluated RPD preference among metal and acrylic resin RPD wearers. Accordingly, the metal dentures were preferred in 93.3% of the cases [39]. However, in this study the length of the follow-up was too short and didn't consider adaptation period. Research suggests that patients' perception of their new denture fluctuates in the first 2 weeks after delivery but stabilizes at the end of the 4 week [14]. Therefore, further studies with a minimum of 6 months follow-up are recommended.

Caution should be considered in the interpretation of the results since several sources of bias and methodological issues have been identified in the included studies. This could explain the inconsistency and statistical heterogeneity in the findings as well. Most of the studies were cross-sectional [11, 12, 35, 36, 41-50] and had a low level of evidence [53]. Confounding by indication and questionable statistical power were identified in most of the studies included in this review [11, 12, 35, 36, 40-50]. To overcome these limitations, rigorous randomized clinical trials are needed.

In this review, the two oldest types of removable partial dentures, cast metal and acrylic resin, were compared. Currently, different alternatives are available which include; nonmetal thermoplastic resins, polyether ether ketone (PEEK), as well as 3D printed metal and implant-assisted removable partial dentures [5, 54]. While the majority of these alternatives still lack extensive scientific evidence, implant-assisted RPDs have shown improved patient satisfaction and might change the practice of removable partial dentures [5, 54-58]. Also, a recent study by our group revealed that patient satisfaction with 3D printed RPDs is higher than with cast RPDs [41]. This observation, along with our findings here, could indicate that while currently available materials present comparable results, the manufacturing process of RPD might be a key factor in treatment success, and further research should be done in this area. Other treatment options to restore partial edentulism include fixed partial dentures and implant supported crowns, which despite their increasing success, might not be accessible to older patients with compromised general health and limited financial resources, rendering removable partial dentures the best practical therapeutic option in many clinical scenarios [54].

This review has several strengths: it included non-English literature, which broadens the scope of the review and could generalize the results to global populations. It also used recent and robust tools, such as ROBINS-I and the Cochrane Risk of Bias Assessment Tool for Randomized Controlled Trials, for the methodological assessment of the included studies. On the other hand, this review has some limitations which include not reaching the definite conclusion due to the low quality and inadequate reporting of the included studies and the risk of publication bias which is a possibility for any well-conducted systematic review.

4.6 Conclusion

The reviewed studies showed that there was no significant difference between metal and acrylic resin removable partial denture treatment in patient satisfaction and oral health-related quality of life. Metal dentures were associated with higher patient compliance rates and were preferred more by patients compared to acrylic resin dentures. However, the reviewed studies had low level of evidence and therefore, high quality randomized controlled trials are needed to conclusively address the question of this review.

4.7 Acknowledgement

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4.8 Supplementary information

Table S4.1: Systematic review search strategy in EMBASE, CENTRAL and Web of Science

DATABASE	Search strategy
EMBASE	1: (removable partial denture [EMTREE]) OR (edentulousness [EMTREE]) OR (dental clasp [EMTREE]) OR (partial* adj5 (dentition* or dentate* or edentul*)) OR (removabl* adj3 partial* adj5 (denture* or prosth*)) OR (RPD) OR ((kennedy or aramany) adj1 class*) 2: (acrylic acid resin [EMTREE]) OR (methacrylic acid [EMTREE]) OR (methacrylic acid methyl ester [EMTREE]) OR (denture base [EMTREE]) OR (denture design [EMTREE]) OR (acrylic* or acrylate*) OR (MMA or PMMA) 3: (vitallium [EMTREE]) OR (dental alloy [EMTREE]) OR (metal* or alloy*) OR (cobalt or chrome or chromium or titanium or molybdenum) OR (vital?ium) 4: #1 AND (#2 OR #3)
CENTRAL	MeSH descriptor: [Denture, Partial, Removable] OR MeSH descriptor: [Jaw, Edentulous, Partially] OR RPD OR vitallium OR removable partial prosthesis OR partial removable denture
WEB OF SCIENCE	#1: TS=((removabl* NEAR/3 partial* NEAR/5 (denture* or prosth*)) OR RPD OR ((kennedy or aramany) NEAR/1 class*) OR (partial* NEAR/5 (dentition* or dentate* or edentul*))) #2: TS=(MMA or PMMA or acrylic* or acrylate* or methacrylic* or methacrylate* OR Methylmethacrylic* or methylmethacrylate* OR denture base* OR denture design*) #3: TS=(cobalt or chrome or chromium or titanium or molybdenum or metal* or alloy* OR vital$ium) #4: 2 OR 3 #5: 4 AND 1

Table S4.2: Inclusion and exclusion criteria of studies in the systematic review

Inclusion criteria	Exclusion criteria
Foreign studies with English abstract	Foreign studies without English abstract were excluded to minimize cost and efforts of translation. We wanted to translate only the potentially eligible articles, and as researchers who screened the articles read only English, we excluded the foreign studies that do not have English abstract. We did not want to translate articles that might be totally irrelevant, wasting our time and efforts.
Randomized trials, observational studies and cross sectional studies	Case reports, case series, expert opinions, commentaries, editorials, reviews, and conference abstracts
Studies should report data for both metal and acrylic RPD	Population of dentulous volunteers
Metal RPD: conventional clasp-retained cobalt chromium RPD	Telescopic RPD, implant-supported RPD or overdenture RPD, Titanium RPD excluded
Acrylic resin RPD: mucosal borne or tissue supported acrylic resin RPD with or without wrought wire clasps	Acrylic resin RPD with metal reinforcement in form of bars, or plate, with or without occlusal rests and cast clasps
	Unilateral RPDs

Table S4.3: Characteristics of the study population of included studies assessing patients satisfaction

First author	Kennedy class	Opposing arch	Anterior/posterior missing teeth	No. of missing teeth	Denture age (years)	RPD experience
Van Waas	I and II: 85% III and IV: 15%	NR	62% posterior 38% anterior	NR	NR	NR
Zlataric, 2003	I 67% II 22.6% III 8.4% IV 1.1% V 0.7%	NR	NR	1-5: 7.6% 6-10: 29.8% >10:62.6%	NR	51% No 49% Yes
Wakabayashi	I 51% II 24% III 12% IV 13%	60% RPD 13% CD 27% NT	NR	NR	NR	NR
Watson	I 38% II 35.2% III 15.5% IV 11.3%	NR	NR	NR	1-3	NR
Zlataric, 2000	I 65.8% II 24.6% III 8.2% IV 0.4% V 0.8%	NR	NR	1-5: 7.3% 6-10: 29.7% >10:63%	<1: 37.5% 1-5: 44% >5: 18.5%	51.5% No 48.5% Yes
Aljabri,	NR	NR	NR	NR	< 1	NR

Abbreviations: NR: not reported, RPD: removable partial denture, CD: complete denture, NT: natural teeth

Table S4.4: Characteristics of the study population of included studies assessing OHRQoL

First author	Kennedy class	Opposing arch	Anterior/posterior missing teeth	No. of missing teeth	Denture age (years)	RPD experience
Montero	NR	NR	NR	>4: 38.5% ≤4: 61.4%	1 month	NR
Shaghaghian	NR	3% CD 42% RPD 55%NR	NR	NR	<1: 54.8% >1: 45.2%	NR
Abuzar	NR	NR	NR	NR	<2 year: 38.8% 2-10:31% >10 year: 30.2%	NR
Ali	I and II: 73% III and IV: 27%	46% RPD 19% CD 35% NT	67% anterior 33% posterior	13 ±6* Upper: 9 ±4 Lower: 8 ±3	2 months-1	Yes 75% No 25%
Elwahbi and Elamin	NR	53.9% RPD	NR	NR	<0.5: 38.9% 0.5-1: 45.1% >1: 15.9%	NR

*Mean number of missing teeth/mouth, abbreviations: NR: not reported, RPD: removable partial denture, CD: complete denture, NT: natural teeth

Table S4.5: Characteristics of the study population of included studies assessing patient compliance

First author	Kennedy class	Opposing arch (n)	Anterior/posterior missing teeth	Number of missing teeth	Denture age (years)	RPD experience
Akeel, 2010	I: 16 II: 23 III: 31 IV: 5	28 RPD 11 CD 8 NT	NR	NR	1	Yes: 39 No: 46
Sawada et al, 2003	II: 100%	70 Dentures 58 NT	NR	NR	NR	NR
Amemori et al, 1968	NR	411 NT 565 RPD 122 CD	NR	1-8 teeth: 629 9-13 teeth: 501	0.5-5	Yes: 604 No: 493

NR: not reported, RPD: removable partial denture, CD: complete denture, NT: natural teeth

Table S4.6: Quality of evidence measured by Oxford Center for Evidence-based Medicine among included studies

Level of evidence	Number of reports	References
2b	1	[35]
4	14	[7, 8, 32, 36-46]

Table S4.7: Results of included studies assessing patient satisfaction

First author	Satisfaction scale	Results					
		Unit of analysis	Statistic	Satisfaction scores		Effect size	P-value
				Metal	Acrylic resin		
Watson et al, 1986	Dichotomous	Denture	Proportion	71.4%	60%	OR: 1.66 95% CI: 0.5- 5.4	>0.05
Van Waas et al, 1994	Categorical from 0-22	Denture	Mean (SD)	10.3 (4.2)	9.4 (4.2)	MD: 0.9 95% CI: (-0.35, 2.19)	>0.05
Wakabayashi et al, 1998	Continuous VAS 0-100	Upper denture	Mean (SE)	48.9 (12.2)	48.3 (8.2)	MD: 0.60 95% CI: (-28.21, 29.42)	>0.05
		Lower denture		37.8 (8.9)	46.8 (8.7)	MD: -9.00 95% CI: (-34.19, 16.19)	
Zlataric et al, 2000	Categorical from 1-5	Denture	NR	NR	NR	NR	>0.05
Zlataric et al, 2003	Categorical from 1-5	Denture	NR	NR	NR	NR	>0.05
Aljabri et al, 2017	Categorical from 1-4	Patient	Mean	3.45	2.88	MD: 0.57	>0.05

Notes: Higher scores mean higher satisfaction in all the studies except Wakabayashi et al which is the opposite. Abbreviations: MD: mean difference of metal-acrylic resin, NR: not reported, SD: standard deviation, SE: standard error, OR: odds ratio of being satisfied in metal denture group over acrylic resin denture group, VAS: visual analog scale

Table S4.8: Results of included studies assessing OHRQoL

First Author	Time since denture delivery (years)	Sum impact scores, mean(SD)			
		Metal RPD	Acrylic resin RPD	Favors**	MD 95% CI
Montero†	1 month	3.9 ± 4.1	1.9 ± 3.9	M	2.0 (-0.09, 4.09)
Shaghaghian	<1: 54.8% >1: 45.2%	15.5 ±10.5	11.5 ±9.4	A	4 (1.01, 6.99) *
Abuzar	<2: 38.8% 2-10:31% >10: 30.2%	13.82 ±13.03	15.37 ±13.5	M	-1.55 (-5.02, 1.9)
Wahbi and Elamin	<0.5: 38.9% 0.5-1: 45.1% >1: 15.9%	17.2 ±10.6	10.6 ±7.5	A	6.6 (1.64, 11.56)*
Ali	2 months-1year	19‡	34‡	M	-15‡

Note: Higher sum impact scores indicate greater impairment in oral health-related quality of life, except for Montero et al study which used improvement from baseline scores and therefore higher scores indicate greater improvement from baseline in oral health-related quality of life. *statistically significant at P<0.05, ** favors indicate the group that had better oral health-related quality of life, † Scores represent improvement from baseline scores, after treatment OHIP-14 was administered, but participants were asked to respond to items by "better", " the same", or "worse" relating their experience after treatment to their experience at baseline (before treatment. Answers were coded as "better=1", "the same=0", " worse= -1". Therefore, higher scores represent greater improvement from baseline, ‡ Median and median difference of metal-acrylic resin dentures Abbreviations: OHRQoL: oral health-related quality of life, MD: mean difference of metal-acrylic resin dentures, CI: confidence interval, SD: standard deviation, A: Acrylic resin RPD, M: Metal RPD

Table S4.9: Results of included studies assessing patient compliance

First author	Time since denture delivery (years)	Unit of analysis	Dentures not worn, n(%)		OR (95% CI)*	P-value
			Metal	Acrylic resin		
Akeel, 2010	1	Denture	15 (30%)	9 (42.8%)	0.76 (0.28-2.11)	P=0.514
Sawada et al, 2003	5	Patients	5 (18.50%) G1: 3 G2: 2	51 (38.90%) G1: 34 (32.4%) G2: 17 (16.2%)	0.36 (0.13-1.00)	P=0.050
Amemori et al, 1968	0.5-5.5	Denture	125 (21.78%)	193 (32.56%)	0.58 (0.45-0.75)	P<0.001

*OR: odd ratio of denture non-wear in metal over acrylic resin

G1: dentures were not worn at all, G2: dentures were used sometimes

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Chapter Five

Patient satisfaction with laser-sintered removable partial dentures: A crossover pilot clinical trial

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Patient satisfaction with laser-sintered removable partial dentures: A crossover pilot clinical trial

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5.1 Abstract

Statement of problem. Clinical data regarding newly introduced laser-sintered removable partial dentures are needed before this technique can be recommended. Currently, only a few clinical reports have been published, with no clinical studies.

Purpose. The purpose of this clinical trial was to compare short-term satisfaction in patients wearing removable partial dentures (RPDs) fabricated with traditional or computer-aided design and computer-aided manufacturing (CAD-CAM) laser-sintering technology.

Material and methods. Twelve participants with partial edentulism were enrolled in this pilot crossover double-blinded clinical trial. The participants were randomly assigned to wear cast or CAD-CAM laser-sintered RPDs for alternate periods of 30 days. The outcome of interest was patient satisfaction as measured with the McGill Denture Satisfaction Instrument. The assessment was conducted at 1, 2, and 4 weeks. The participant preference in regard to the type of prosthesis was assessed at the final evaluation. The linear mixed effects regression models for repeated measures were used to analyze the data using the intention-to-treat principle. To assess the robustness of the findings as to potential incomplete adherence, sensitivity analyses were conducted.

Results. A statistically significant difference was found in terms of patient satisfaction between the 2 methods of RPDs fabrication. Participants were significantly more satisfied with laser-sintered compared with cast prostheses in regards to general satisfaction, ability to speak, ability to clean, comfort, ability to masticate, masticatory efficiency, and oral condition ($P<.05$). At the end of the study, 5 participants preferred the laser-sintered, 1 preferred the cast RPD, and 3 had no preference.

Conclusions. The use of CAD-CAM laser-sintering technology in the fabrication of partial prostheses may lead to better outcomes in terms of patient satisfaction in the short term. The conclusion from this pilot study requires confirmation by a larger randomized controlled trial. Clinicaltrials.gov NCT02769715.

5.2 Clinical significance

Laser-sintered removable partial dentures could be considered as a promising alternative in the fabrication of RPDs.

5.3 Introduction

Removable partial dentures (RPDs) are a conservative and low-cost option that restores missing teeth in patients with partial edentulism, improving their quality of life [1-7]. They have an important impact on millions worldwide and important commercial implications [8-11]. Over 13% of adults in North America and Europe wear removable partial dentures [10, 12].

RPD frameworks are traditionally made of cast alloys using the lost-wax technique, a laborious manual process that is prone to human error [13]. In order to overcome the limitations of the lost wax technique, the fabrication of RPD frameworks using digital rapid prototyping techniques has recently been introduced [14]. Rapid prototyping (RP) is the collective term for different processing technologies that fabricate accurate 3-dimensional (3D) objects directly from computer-aided design (CAD) in a short time [15]. This manufacturing technique allows the production of complex 3D shapes such as RPD frameworks [16].

Rapid prototyping additive manufacturing technologies include stereolithography (SLA), selective laser melting, selective laser sintering, selective deposition modeling, 3D printing, and direct inkjet printing [16]. Stereolithography was the first prototyping technique introduced commercially and the first one used to fabricate removable partial denture frameworks in the early 2000s [17]. Stereolithography was used to fabricate resin sacrificial patterns for RPD frameworks that were then conventionally cast to get the definitive RPD metal framework [17, 18]. The resulting framework showed acceptable fit [19]. However, this technique can still introduce error into the casting process itself.

In 2006, the selective laser melting technique was introduced to allow direct manufacturing of the computer-designed metal framework, which eliminates the casting steps [20]. This

was done using a physical sculptor to virtually build the framework [20, 21]. The methodology was expensive and time-consuming, and to overcome these limitations, software was developed to virtually design RPDs without the need for a sculptor [22]. However, as these programs were not specifically designed for RPDs, the time needed to determine the path of insertion, eliminate undesirable undercuts, and draw the framework components was extensive. The first software (Tang Long CAD) developed specifically for designing RPD frameworks for rapid prototyping was released in 2010 [23].

Selective laser sintering technologies allow the fabrication of 3D metal objects in successive cross-sections [15]. The superior precision of laser-sintering technologies can reduce the errors of manual processing, thereby increasing the quality of the prostheses while reducing manufacturing costs and rendering the treatment accessible to a larger section of the population [14]. Selective laser sintering has been used to fabricate inlays, crowns, implants, and surgical guides [24-28].

Currently, several laboratories worldwide fabricate RPDs digitally. Clinical trials are needed to evaluate this new technology in RPD fabrication before its use can be recommended. However, the clinical performance of RPDs produced digitally from computer-aided design and computer-aided manufacturing (CAD-CAM) and RP technologies has been reported in only a few clinical reports [14, 19, 20, 29, 30]. The authors are unaware of published clinical studies comparing traditional RPDs with those produced by CAD-CAM processes. Therefore, the purpose of this pilot crossover randomized clinical trial was to compare CAD-CAM RPDs with conventional RPDs in terms of patient satisfaction after 1 month of prosthesis use.

5.4 Material and methods

Ethical approval for the study protocol was obtained from McGill University Institutional Review Board (12-452 BMD), and the trial protocol was registered in the US Clinical Trials Registry NCT02769715. The Consolidated Standards Of Reporting Trials (CONSORT) statement was followed in reporting the study results [31].

Patients who visited the predoctoral clinic at McGill University (Montreal, Canada) for the restoration of missing teeth with RPDs in the academic years 2013 to 2015 were invited to participate in the study. Study participants received a written, detailed description of the study and signed a consent form.

For inclusion in the study, participants had to have partial edentulism; have adequate buccolingual and occlusal space for prosthetic teeth and metal framework; be able to maintain adequate oral hygiene and clean their prostheses; not have major systemic health problems that could interfere with general oral health (American Society of Anesthesiology [ASA] 1 or 2); and be capable of giving written, informed consent and fill out questionnaires in English or French.

The study design consisted a double-blind pilot crossover trial. Participants were randomized to wear their RPDs in 1 of 2 sequences by tossing a coin: cast then laser-sintered RPDs (Cast-Laser) or laser-sintered then cast RPDs (Laser-Cast). The length of each sequence was 1 month without any washout period. The treatment was received from a predoctoral student supervised by a prosthodontist. The student, supervisor and participants were all blinded to the type of RPD. The principal investigator (F.T.) was responsible for preparing the laboratory work authorizations and sending the definitive impressions to the dental laboratory to ensure the masking process.

The participants were treated according to standardized clinical procedures. Both types of prostheses were fabricated simultaneously from the same definitive cast. The cast was scanned first with a 3D scanner (3Series; Dental Wings) to fabricate the laser-sintered RPDs (Fig. 5.1 A, B).

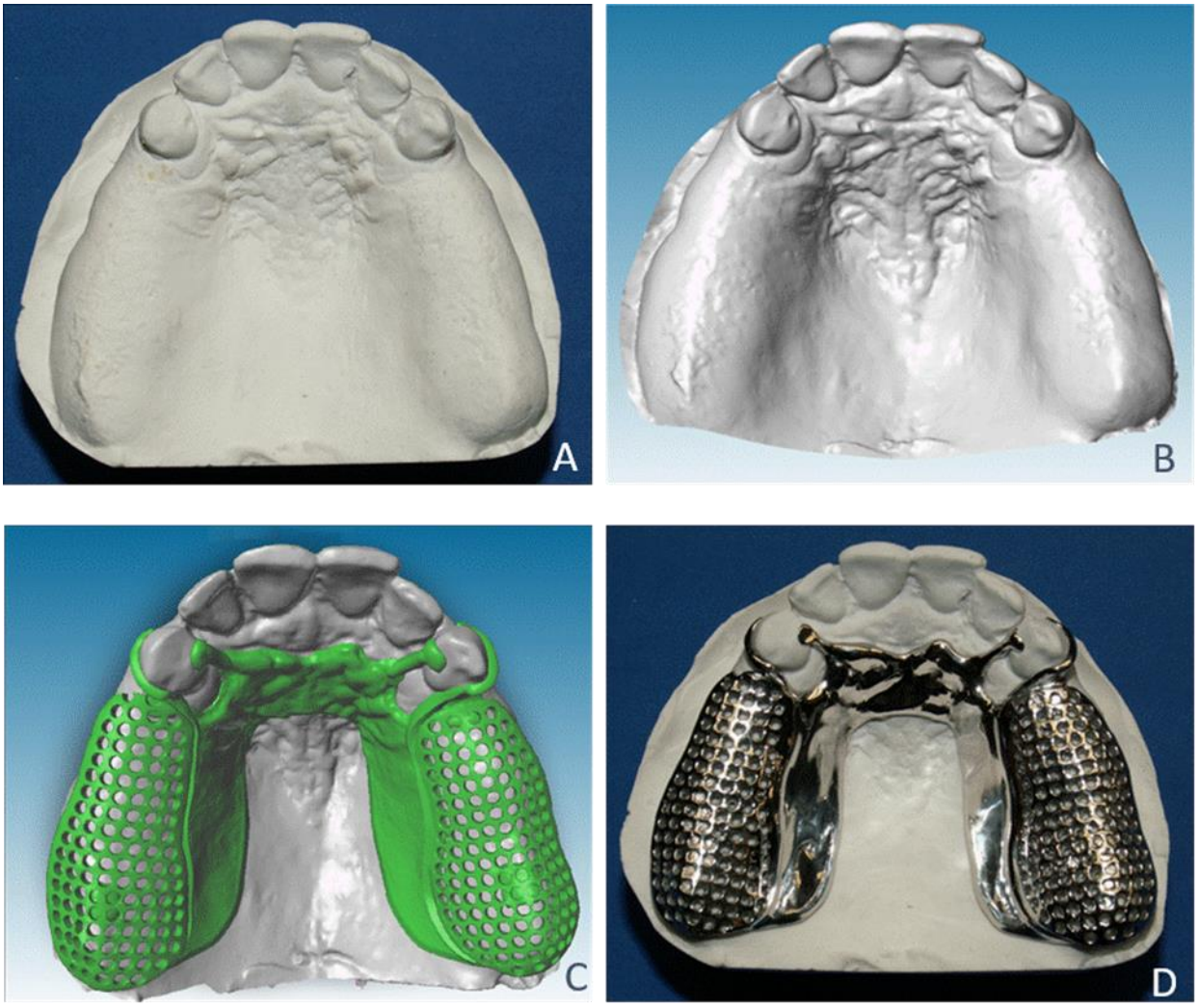

Figure 5.1. Steps for fabricating laser-sintered PRDP. A, Definitive cast of participant with partial edentulism. B, STL image of definitive cast scanned with 3D scanner. C, Virtual build-up of PRDP framework. D, Laser-sintered PRDP framework.

The definitive cast was then reused to fabricate the traditional RPDs following standard procedures. To fabricate the framework for laser-sintered RPDs, the path of insertion was determined on the digital file, and the survey line was drawn. Then, the entire framework design was built virtually in 3D format using 3Shape CAD Points software (3Shape) (Fig. 5.1C). The standard tessellation language (STL) file was then transferred to the rapid prototyping machine (PM100 Dental & PM100T Dental; Phenix), and the definitive framework was produced using cobalt-chromium alloy powder (Sintech Metal) and the selective laser sintering technique (Fig. 5.1D). Similar acrylic resin teeth (Ivostar & Posteriors; Ivoclar Vivadent AG) were used for both types of RPDs. The tooth arrangement and prosthesis base waxing were replicated using a plaster index. All laboratory procedures were performed by 1 technician at the same dental laboratory.

Prosthesis adjustment was performed at the delivery visit for both prostheses, which were identified by numbers. Then, 1 prosthesis was chosen randomly based on a coin toss and given to the participants. Participants were scheduled for 1, 2, and 4-week follow-up visits and any necessary adjustments were conducted at these visits. At the 1-month follow-up, the participants were given the second prosthesis and scheduled for the same follow-up plan. Participant preference in regards to the type of prosthesis was assessed at the final follow-up visit.

During the follow-up visits, the participants were asked to fill in the McGill Denture Satisfaction questionnaire. This 9-item questionnaire has been validated and used in various clinical trials to measure patient satisfaction in regards to ease of cleaning, ability to speak, comfort, esthetics, stability, ability to masticate several types of food, masticatory efficiency, oral condition, and general satisfaction [32-35]. Participants were asked to rate

each item from 0 to 100 on a Visual Analog Scale (VAS), where zero means totally unsatisfied. Participants' complaints and compliments were also recorded.

To calculate the sample size, a minimum clinically significant difference in general satisfaction with a removable partial denture was assumed as 10 mm with a standard deviation of 8, based on the results of a previous crossover trial [36]. Accordingly, at α=.05, a minimum of 8 participants were required to achieve a power of 80%. Accordingly, 12 participants were recruited to account for potential dropouts. To detect the treatment effect, linear mixed models were built for 4-week data. In the initial model, intervention (prosthesis type), period, sequence and period by treatment interaction were considered as fixed factors and participant as a random factor. Period by treatment interaction was used to test for the carryover effect; as this interaction was not statistically significant (P=.391), the final model was fit without it. Between-subject variation during the adaptation period were presented using line graphs. The intention to treat principle was respected and α=.05 was used for all tests. Sensitivity analysis for complete treatment only (n=9) was conducted to assess the robustness of the findings to potential incomplete adherence. Statistical software (STATA 14; StataCorp LLC) was used for the analysis.

5.5 Results

Twelve participants (8 men and 4 women) were recruited. Seven participants received cast RPDs first, while the other 5 participants received laser-sintered RPDs first. One participant was lost to follow-up after receiving the second prosthesis, and 2 participants withdrew from the study because 1 of the 2 prostheses did not fit: a laser-sintered RPD in one participant and a cast RPD in the other participant (Fig. 5.2). The mean participant age was 65.6 ±11.3 years. More than half of the RPDs (76%) were Kennedy class I or II. The

participants' demographic data and oral condition are shown in Table 5.1. Individual demographic data are presented in supplementary Table S5.1.

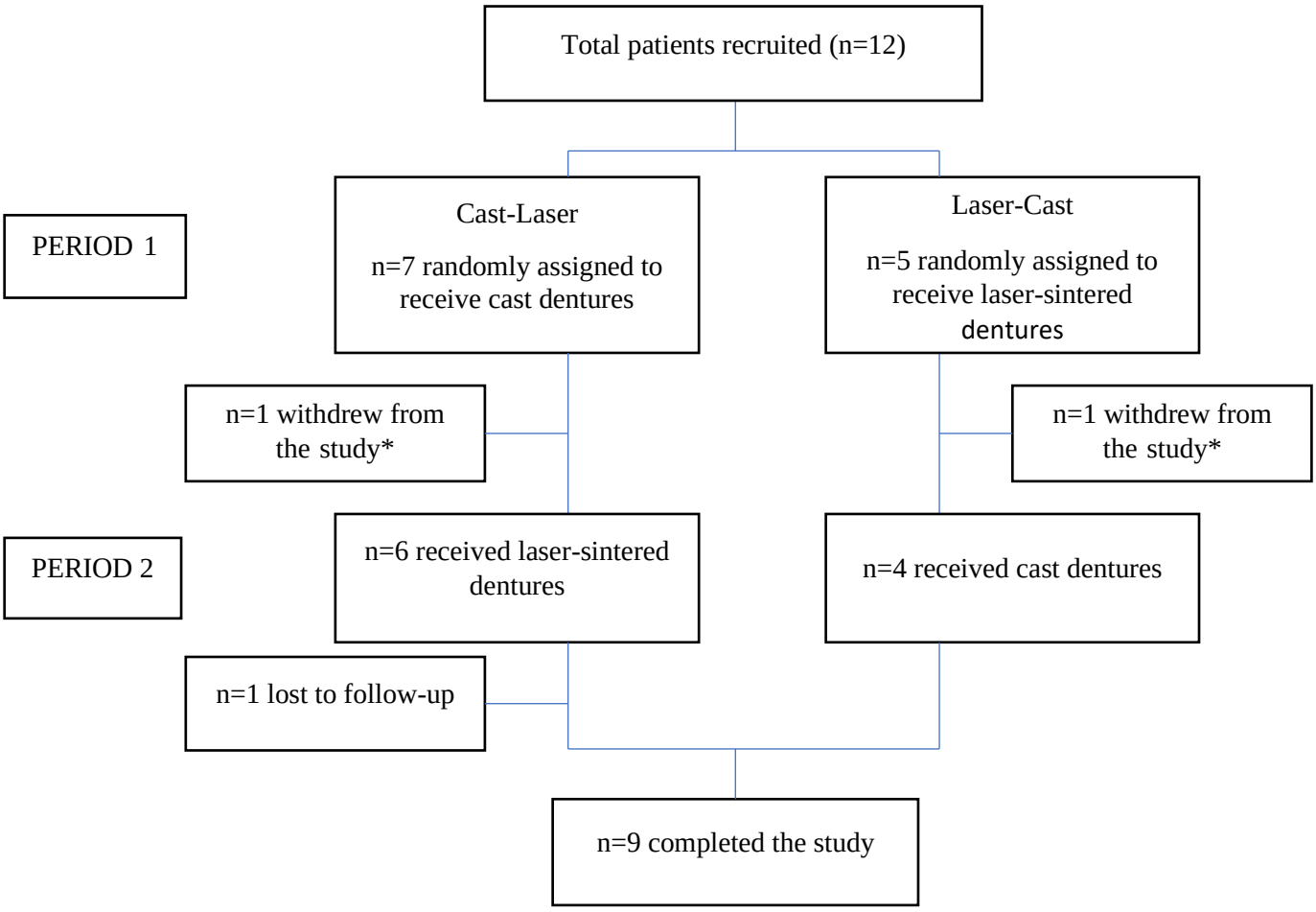

Figure 5.2. Participant recruitment flow chart.

Table 5.1. Demographic data and prosthesis-related data at baseline for all randomized participants categorized based on treatment sequence

Variables		**Cast-Laser Group (n=7) n (%)**	**Laser-Cast Group (n=5) n (%)**
Age mean (SD)		63 (8)	69.4 (14.9)
Sex	M	4 (57%)	4 (80%)
	F	3 (43%)	1 (20%)
Arch	U	2 (28.5%)	1 (20%)
	L	1 (14.3%)	3 (60%)
	Both	4 (57%)	1 (20%)
Cases with missing anterior teeth		3 (42.8%)	1 (20%)
Kennedy	I	4 (36.4%)	4 (16.6%)
Class	II	4 (36.4%)	1 (66.6%)
	III	2 (18.2%)	0
	IV	1 (9%)	1 (16.6%)
Previous	Yes	5 (71.4%)	4 (80%)
PRDP	No	2 (28.6%)	1 (20%)
Opposing	RPD	4 (57%)	2 (40%)
Arch	NT	3 (42.8%)	1 (20%)
	CD	0	2 (40%)
Dropouts		2 (28.5%)	1 (20%)

Cast-Laser Group: patients who received cast prosthesis first. Laser-Cast group: patients who received laser-sintered prosthesis first
Abbreviations; M: male, F: female, U: maxillary arch, L: mandibular arch, CD: complete prosthesis, NT: natural teeth

For general satisfaction, the linear mixed model showed a statistically significant treatment effect (*P*=.008), but no significant period (*P*=.131) or sequence effect (*P*=.686) (Table 2 and supplementary Table S2**)**. Participants rated laser-sintered RPDs higher than cast RPDs for general satisfaction, with a mean difference of 12.5 mm (*P*=.008, 95% CI: 3.3-21.8).

Participants reported significantly higher satisfaction with the laser-sintered prosthesis compared with the cast prosthesis in terms of the ability to clean and speak, comfort, stability, masticatory ability, masticatory efficiency, and the perception of the oral condition ($P<.05$), as shown in Table 5.2 and in supplementary Table S5.2. Period and sequence effects were not statistically significant ($P>.05$) for any of the satisfaction items except for ability to masticate, which showed a significant period effect ($P=0.017$) (supplementary Table S5.2**)**. Sensitivity analysis for complete treatment only (n=9) was similar to the results of the intention to treat analysis (Table S5.3). Participants were significantly more satisfied with the laser-sintered than the cast RPDs in regards to all satisfaction items ($P<.05$) except esthetics ($P=.148$) (Table S5.3).

The line graph analysis showed that, for most of the questionnaire items, the mean satisfaction scores of the laser-sintered RPDs increased from the first week to the fourth week, except for the oral condition. This item showed a stable score throughout the follow-up period (Fig. 5.3). However, the mean satisfactions scores for the cast RPDs showed a gradual decrease in general satisfaction, ease of cleaning, and stability and a gradual increase in comfort scores during the follow-up periods. The scores for masticatory efficiency and ability, speech, and oral condition were stable throughout the follow-up period.

The means of within-subject satisfaction score differences between laser-sintered and cast RPDs are presented in supplementary Figure S5.1. Table S5.4 represent the mean and standard deviation (SD) for all variables at all follow-up times.

Table 5.2. Treatment effect from mixed model analysis for all satisfaction items

Satisfaction Items	Treatment Coefficient*	SE**	Z	P	95% CI	
					Lower bound	Upper bound
General satisfaction	12.5	4.7	2.66	.008	3.3	21.8
Ease of cleaning	7.3	2.8	2.58	.010	1.8	12.9
Ability to speak	12.1	5.1	2.52	.012	2.9	22.9
Comfort	7.3	3.0	2.42	.016	1.4	13.3
Esthetics	4.6	5.1	0.89	.372	-5.5	14.6
Stability	15.6	7.7	2.02	.044	0.4	30.7
Ability to masticate	15.4	6.3	2.42	.015	2.9	27.8
Masticatory efficiency	6.8	3.0	2.29	.022	1.0	12.7
Oral condition	6.2	3.0	2.09	.036	0.4	12.0

*Treatment coefficient in mm of the visual analog scale of McGill Denture Satisfaction instrument. A positive value (>0) is indicative of "in favor" of the laser-sintered RPDs, as the laser-sintered prosthesis was used as the reference for the dummy variable of treatment; therefore, positive regression coefficient indicates higher satisfaction for laser-sintered compared with cast.
**Standard error

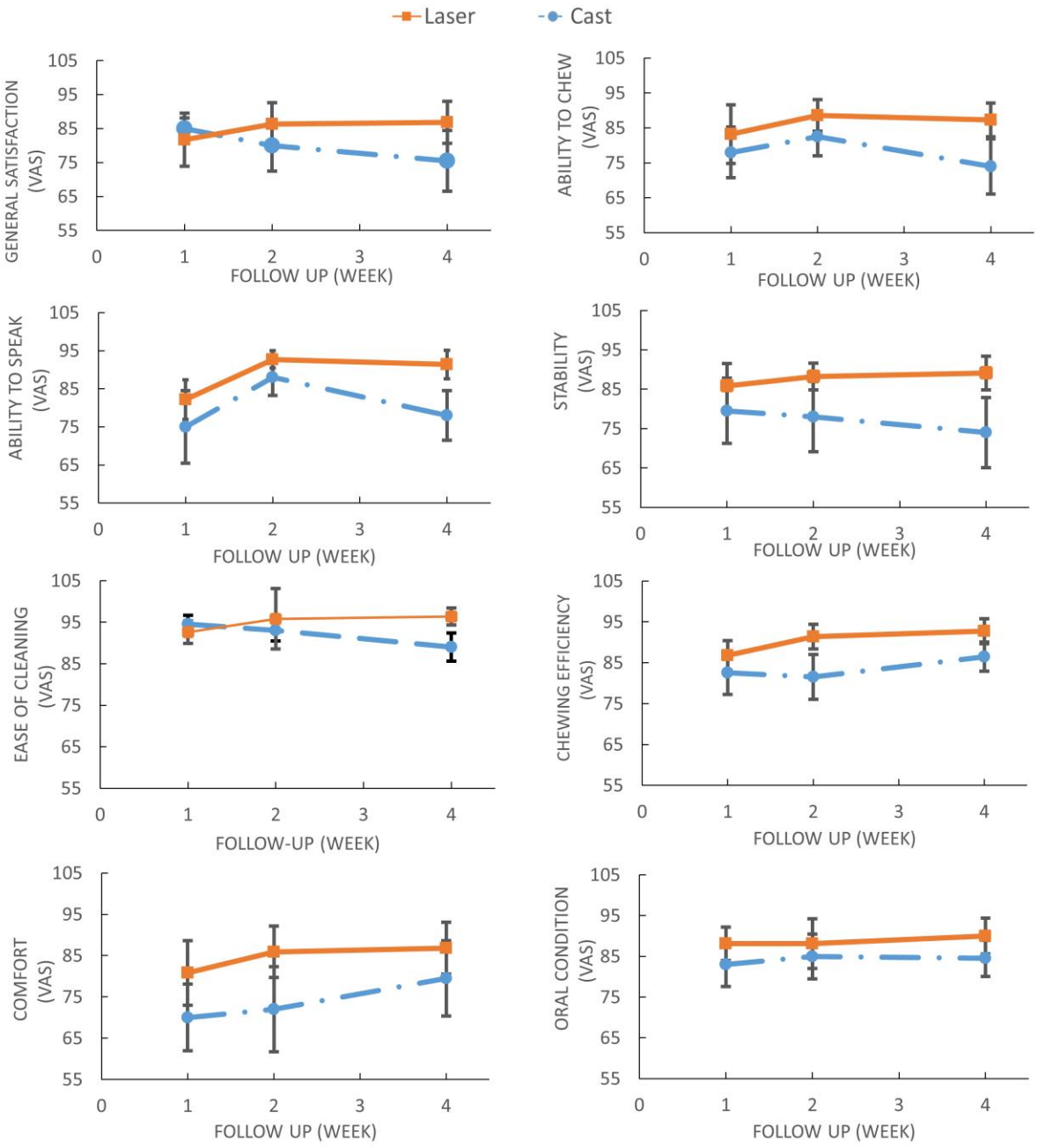

Figure 5.3. Trend over time of both laser-sintered and cast prostheses for satisfaction items that were significantly different among the treatments (general satisfaction, ease of cleaning, ability to speak, comfort, stability, masticatory ability, masticatory efficiency,

and oral condition). VAS, visual analog scale measurement in survey 0-100 mm, error bars represent standard deviations.

This study showed that the most common complaints by participants regarding their RPDs were related to fit and retention, followed by soft tissue ulceration and then mastication problems. Participants reported fewer complaints and more compliments when they were using the laser-sintered RPDs compared with the cast RPDs, as shown in Table 5.3. Every participant who started with a laser-sintered RPD (n=4), preferred it at the end of the study. Among the participants who received the cast RPD first, 1 preferred the cast RPD, 3 found no difference between the 2 prostheses, and 1 preferred the laser-sintered RPD.

Table 5.3. Complaints and compliments reported by participants during the follow-up period

Participants' subjective comments	Laser (10 participants)	Cast (11 participants)
Complaints		
Soft tissue ulceration/ pain and soreness		
Prosthesis or clasp hurting the tongue or gum	2	3
Loss of retention		
Prosthesis does not fit properly and needs to be adjusted	0	1
Prosthesis is loose	1	3
Denture is unstable	0	1
Denture feels too tight	0	1
Mastication problems		
Difficult or painful to chew	1	1
Cheek biting	0	1
Esthetic problems		
Unesthetic front tooth	1	1
Hygiene problems		
Food trapped under prosthesis	0	1
Miscellaneous		
Metal taste in mouth	1	0
Denture is irritating and causes nausea	0	1
Denture is thick	0	1
Total complaints	**6**	**15**
Compliments		
Denture is easy to remove	0	1
Denture is very light	2	0
Denture is tight	1	0
Denture fits very well	2	0
Total compliments	**5**	**1**

5.6 Discussion

Laser-sintering is a relatively new technology in dentistry and has only been assessed through observational studies in fixed and implant dentistry [26-28]. To the best of the authors' knowledge, this study is the first randomized controlled clinical trial that evaluates patient satisfaction of laser-sintered removable partial dentures. In the current study,

participants were significantly more satisfied with the laser-sintered prostheses than the cast prostheses in terms of general satisfaction, ability to clean and speak, comfort, masticatory ability, masticatory efficiency, and oral condition. The greatest effect size was recorded for stability, followed by ability to masticate, general satisfaction, and ability to speak. The other satisfaction items had a smaller effect size with minimal clinical value [34].

In this study patient satisfaction with cast prostheses falls within the range of that of previous studies. Mean satisfaction scores for laser-sintered prostheses were among the highest reported for removable partial dentures, regardless of the study design or measurement tools (Table S5.5) [1-6, 8, 11]. This is even though most of the RPDs in this study were Kennedy class I or II, which has been shown to affect satisfaction negatively compared with Kennedy class III or IV [37]. This significant difference in participants' general satisfaction between cast and laser-sintered prostheses could be related to the enhanced mechanical properties of laser-sintered alloys [26]. Laser-sintered cobalt-chromium alloy is harder, denser, and has better microstructural organization and higher yield strength and ultimate tensile strength than cast alloys [26]. These superior mechanical properties along with better precision may improve clasp retention and stability, which is known to greatly increase patient overall satisfaction and comfort [7]. Indeed, the participants in this study were more satisfied with the stability and subsequently masticatory capabilities of the laser-sintered prostheses than with the cast prostheses.

The participants were more satisfied with the ability to speak with the laser-sintered RPD than the cast RPD. This is probably due to the better stability and retention reported for laser-sintered RPDs. Indeed, the ability to speak correlates positively with the stability and retention of the prosthesis [34, 38].

In this study, participants were significantly more satisfied with the masticatory ability and efficiency of laser-sintered prostheses compared with cast prostheses with identical tooth arrangements and acrylic resin bases. This can be explained by the stability of the prostheses, which also scored significantly higher for laser-sintered compared with that of cast RPDs. Participants' assessment of masticatory ability is usually consistent with their assessment of stability, comfort, and general satisfaction, which, in this study, were higher for laser-sintered RPDs than for cast RPDs [35].

Regarding esthetics, no significant difference was found in participant satisfaction between prostheses. This was expected, as the esthetics of RPDs is more related to tooth arrangement, size and shade, and denture bases than to the metal framework. Participants were significantly more satisfied with laser-sintered RPDs in terms of ability to clean when compared with cast prostheses. A possible explanation is that laser-sintering technology produces more precise fits that may reduce food accumulation beneath the prostheses [26].

The satisfaction rating for laser-sintered RPDs increased gradually over time, whereas it was inconsistent with cast RPDs. This may indicate that participants had an easier adaptation period when using laser-sintered compared with cast RPDs. The gradual decrease in satisfaction with cast RPDs can be related to the fatigue of cast clasps over time, which affects prosthesis retention, thereby affecting general satisfaction [39]. The fatigue behavior of laser-sintered clasps has not yet been studied, but based on the reported improved mechanical properties, it is expected to be an improvement over casting [26].

At the end of the study, 5 participants preferred, while blinded, the laser-sintered prosthesis over the cast prosthesis, and the reasons given by the participants (explained in the results) confirm the results of this study and support the hypothesis regarding the accurate fit and enhanced retention of laser-sintered prostheses.

The most frequent complaint about the prostheses was related to fit and retention, followed by ulceration of the tongue or gingiva and masticatory problems, all of which are common findings in removable partial dentures studies [40]. Participants reported fewer complaints, especially related to prosthesis looseness, when they used the laser-sintered prostheses, which supports the other results in this study.

This new technology in fabrication has some limitations. The high initial cost of the laser sintering machine and the necessary software in addition to the time and expertise needed to learn this technology are some of the limitations [14-23]. Another limitation is that currently this technique cannot be used for all patients, since some special designs cannot be produced easily because of the limitations of the available software and the manufacturing process [14-23]. Future work should be directed towards the improvement of the software to expand the application of this technology.

The strengths of this study include the use of patient-centered outcome, the randomized crossover design, double-blinding, and the inclusion of participants' complaints, compliments, and their preferred choice of treatment. Moreover, evaluating participant satisfaction at 3 time points provided an insight into the prosthesis performance over time. There are some limitations to this study. First, the small sample size and short follow-up limit the generalizability to long-term clinical performance. Although, the crossover design used in this study was justified for decreasing interparticipant variation and providing power with a small sample size, it has some disadvantages, including the potential for a carryover effect [35]. A washout period is usually recommended to erase the physical and psychological carryover effects but is not always possible. As in this study, it would not be ethical to leave the participants without a prosthesis [35]. Therefore, a larger clinical trial with a longer follow-up is recommended.

5.7 Conclusion

Within the limitations of this pilot crossover double-blinded clinical trial, the following conclusion was drawn:

The use of laser-sintering technology for the fabrication of removable partial dentures may lead to higher short-term satisfaction for patients with partial edentulism when compared with traditional methods.

5.8 Acknowledgement

The authors acknowledge the fund provided by 3DRPD Company and King Saud University, Riyadh, Saudi Arabia.

5.9 Supplementary information

Table S5.1: Demographic data, prosthesis-related data, and preferred prosthesis for all randomized patients categorized based on treatment sequence

Patient	Age	Sex	Arch	Missing teeth (n.)		Kennedy Classification	Previous RPD experience	Opposing Arch	Preferred denture
				Ant.	Post.				
Cast-Laser Group									
1	64	M	U	0	4	I mod 1	Yes	RPD	Cast
1	"	"	L	0	4	I mod 1	"	"	
2	66	F	L	0	7	I	No	NT	LS
6	51	M	U	7	0	IV	No	RPD	ND
6	"	"	L	0	2	III	"	"	
7	72	M	U	1	6	I mod 1	Yes	NT	ND
9	72	F	U	0	4	III mod 1	Yes	NT	ND
10	61	M	U	0	3	II mod 1	Yes	RPD	Dropout
10	"	"	L	0	4	II mod 2	"	"	
12	55	F	U	0	2	II mod 2	Yes	RPD	Dropout
12	"	"	L	3	4	II mod 3	"	"	
Laser-Cast Group									
3	77	F	L	0	5	I	Yes	NT	LS
4	45	M	U	0	4	I	No	RPD	LS
4	"	"	L	4	0	IV	"	"	
5	84	M	L	0	6	I	Yes	CD	LS
8	67	M	U	0	6	I	Yes	RPD	LS
11	74	M	L	0	4	II mod 2	Yes	CD	Dropout

Cast-Laser Group: received cast PRDP first, Laser-Cast group: receive laser-sintered PRDP first

Ant.: anterior, post: posterior, M: male, F: female, U: upper arch, L: lower arch, CD: complete denture, NT: natural teeth, LS: laser-sintered denture, ND: no difference

Table S5.2: Satisfaction survey items: Mixed model coefficients (standard error) and p-value for fixed explanatory variables

	General Satisfaction	Ease of Cleaning	Ability to Speak	Comfort	Esthetics	Stability	Ability to masticate	Masticatory Efficiency	Oral Condition
Constant	65.45 (21.12)	79.0 (8.4)	63.7 (16.0)	54.3 (20.6)	79.5 (13.2)	67.8 (21.2)	86.9 (18.8)	79.4 (10.3)	78.4 (12.7)
Treatment	12.5 (4.7)	7.3 (2.8)	12.1 (5.1)	7.3 (3.0)	4.6 (5.1)	15.6 (7.7)	15.4 (6.3)	6.8 (3.0)	6.2 (3.0)
Period	-7.1 (4.7)	-0.6 (2.8)	3.0 (5.1)	2.4 (3.0)	3.9 (5.1)	-9.4 (7.7)	-15.2 (6.3)	0.6 (3.0)	-3.4 (3.0)
Sequence	5.0 (12.3)	2.7 (4.2)	-1.2 (8.3)	10.2 (12.6)	-1.2 (5.8)	2.8 (10.0)	-5.4 (9.4)	-1.0 (5.6)	3.0 (7.3)
Test									
Constant	.002	<.001	<.001	.008	<.001	.001	<.001	<.001	<.001
Treatment	.008	.010	.012	.016	.372	.044	.015	.022	.036
Period	.131	.820	.564	.428	.450	.221	.017	.835	.243
Sequence	.686	.527	.882	.420	.831	.781	.566	.858	.683

P<0.05 is statistically significant

Table S5.3: Treatment effect from sensitivity complete cases (n=9) analysis using linear mixed model analysis

Satisfaction Items	Treatment Coefficient	SE	Z	P-value	95% CI	
					Lower bound	Upper bound
General satisfaction	13.0	4.8	2.67	.007	3.5	22.5
Ease of cleaning	7.8	3.0	2.61	.009	1.9	13.6
Ability to speak	12.3	5.4	2.28	.022	1.7	22.8
Comfort	7.5	3.1	2.45	.014	1.5	13.5
esthetics	7.0	4.8	1.45	.148	-2.5	16.5
stability	16.5	8.5	1.95	.051	-0.1	33.1
Ability to masticate	16.2	6.7	2.41	.016	3.1	29.4
Masticatory efficiency	7.2	3.0	2.44	.015	1.4	13.1
Oral condition	6.5	3.0	2.15	.031	0.60	12.4

P<0.05 is statistically significant

Table S5.4: Survey scores mean (SD) for laser-sintered and cast prostheses at different follow-up time points (n=12)

Survey items	First week		Second week		Fourth week	
	Laser	Cast	Laser	Cast	Laser	Cast
Ease of cleaning	92.6 (9.0)	94.5 (6.9)	95.8 (7.3)	93.0 (7.8)	96.4 (6.7)	89.0 (10.7)
General satisfaction	81.7 (23.8)	85.0 (10.0)	86.4 (20.6)	80.0 (23.7)	86.8 (20.5)	75.5 (28.3)
Ability to speak	82.2 (17.3)	75.0 (30.2)	92.7 (7.9)	88.0 (15.3)	91.4 (12.3)	78.0 (20.8)
Comfort	80.8 (25.9)	70.0 (25.5)	85.9 (20.6)	72.0 (32.6)	86.8 (20.8)	79.5 (28.9)
Esthetic	91.3 (8.3)	91.0 (9.9)	93.6 (8.1)	92.0 (7.5)	92.3 (12.5)	88.0 (13.8)
Stability	85.8 (19.1)	79.5 (26.3)	88.2 (11.5)	78.0 (28.2)	89.1 (14.4)	74.0 (28.3)
Ability to masticate	83.2 (28.0)	78.0 (23.4)	88.6 (15.2)	82.5 (17.5)	87.3 (16.2)	74.0 (25.1)
Masticatory efficiency	86.8 (12.1)	82.6 (17.2)	91.4 (10.0)	81.5 (17.3)	92.7 (10.1)	86.5 (11.3)
Oral condition	88.2 (13.6)	83.0 (17.2)	88.2 (20.3)	85.0 (17.6)	90.0 (14.8)	84.5 (14.0)

Table S5.5: Summary of patient satisfaction with removable partial dentures

Study name	Design	Patients/ prostheses (n.)	Prosthesis age	Measurement tool	Results	Notes
Frequency data presentation						
Abuzar et al 2012, Victoria, Australia[5]	Cross sectional	232/ 229	3-5 years	Dichotomous survey	59% satisfied	Most had their RPD based on clinician recommendation not their own request
Shaghaghian et al, 2015, Shiraz, Iran[8]	Cross sectional	200/ 284	50% less than 1 year	Dichotomous survey	61% satisfied	
Frank et al, 1998, Seattle, USA[3]	Cross sectional	410/ 410	60% less than 3 years	6 points categorical scale	80.2% satisfied or completely satisfied	34.3% were first RPDs, only lower RPDs
Van Waas et al, 1994, Zwolle, The Netherland[1]	Cross sectional	NR/71	NR	4 points categorical scale	81% satisfied or highly satisfied,	61% acrylic resin RPDs and 60% were distal extension
Celebic and Zlataric, 2oo3, Zagreb, Croatia[11]	Cross sectional	112/ NR	1-4 years	5 points categorical scale	91% were satisfied or highly satisfied	All cases were Kennedy class I
Central tendency data presentation						
Wakabayashi et al, 1998, Tokyo, Japan[9]	Cross sectional	66/ 94	NR	VAS Survey	U: 51.1±12.2* L: 62.2 ±8.9	Participants were patients unsatisfied with their RPD and wanting a replacement
Wismeijer et al, 2011, New Zealand[6]	prospective Clinical trial	12/ 12	12 weeks	McGill denture satisfaction VAS	73.4 ±15.05*	Cases were mandibular class I opposing complete denture
This study, Montreal, Canada	Cross over clinical trial	9/ 12	4 weeks	McGill denture satisfaction VAS	Cast: 73.89±29.59	
This study, Montreal, Canada	Cross over clinical trial	9/ 12	4 weeks	McGill denture satisfaction VAS	Laser: 86.11±22.32	
Wu et al, 2012, Kaohsiung, Taiwan[7]	Cross sectional	193/ 205	NR	ODIP (oral impact on daily performance) 4 points likert scale; 4 means satisfaction	3.5/4	45% distal extension cases
Vanzeveren et al, 2003, Brussels, Belgium[2]	Cross sectional	254/ 292	≥ 3 years or more	Satisfaction VAS survey	89.9/100 ± 1.4*	Mainly class I and II treated by dental students
Zlataric et al, 2003, Zagreb, Croatia[4]	Cross sectional	250/ 261	40% less than 1 year	5 points categorical scale; 5 highly satisfied	Median 5/5	51% first time RPD users, 44% are acrylic RPDs

NR: not reported, U: upper arch, L: lower arch

*The results have been rescaled for easier comparisons

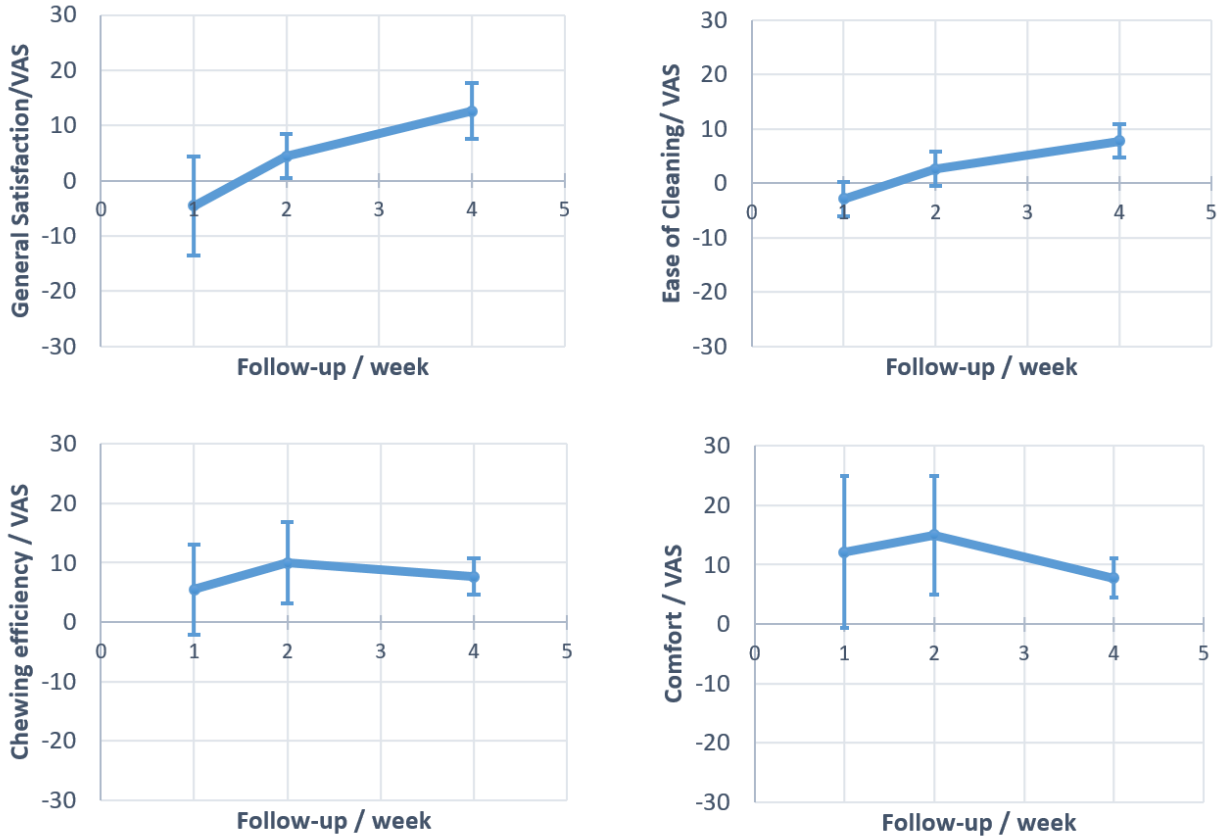

Fig S5.1. Graphs show the trend over the follow-up periods for the within-subject mean difference of satisfaction scores (laser-sintered – cast) for general satisfaction, ease of cleaning, comfort, and masticatory efficiency. Graphs represent mean difference and standard errors

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Chapter Six

Tooth Shade Preferences among the General Public

Tooth Shade Preferences among the General Public

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6.1 Abstract

Objective: A guideline on the most preferred tooth shades among the general public could help in tooth shade selection in the absence of adjacent teeth. The aim of this study was to identify laypersons' tooth shade preferences as a function of the skin shade of the patient.

Methods: Two subsequent and independent online surveys using computer-designed perioral images of different shades of the skin and teeth were conducted in Montreal (Canada) and San Francisco (USA). The first survey (n = 120) assessed individual preferences for tooth shade value, hue, and chroma as a function of the skin shade. The second survey aimed to pinpoint the most preferred tooth shade of Vita 3D-Master shade guide. Logistic regression was used to determine significant factors associated with preferred tooth shades.

Results: Most of the participants preferred teeth with the highest value (54%), a neutral hue (59%), and the lowest chroma (89%); and the most preferred tooth shade (75%) was 1M1 regardless of the model skin color ($p < .001$). This finding was more pronounced on models with light skin shade compared to models with darker skin shade.

Conclusion: Teeth with high value, neutral hue, and low chroma were the most preferred. The 1M1 was the most preferred tooth shade regardless of skin shade.

Keywords: tooth color, layperson, people's preferences, hue, chroma, value

6.2 Clinical significance:

Based on public preferences regarding tooth shade, selecting tooth shades with high value, neutral hue, and low chroma, in the absence of adjacent teeth, could obtain higher patient acceptance.

6.3 Introduction

Dentists today are greatly challenged by the increasing esthetic demands of their patients [1]. Meeting patients' esthetic expectations requires deep understanding of their needs, and preferences [2]. In this sense, patients often consider tooth shade as the most important factor of a beautiful smile [2-4] and the biggest source of dissatisfaction with their smile [2].

In dental treatments, shade selection is usually governed by the appearance of the patients' own teeth. However, there are several conditions in which tooth shade selection is challenged by the lack of clear references in the patient mouth like complete dentures cases, full mouth rehabilitations or esthetic smile reconstruction [5]. In these cases, dentists usually rely on the patient's skin, eye, and hair color as well as age and gender as a guide for shade selection [5]. Among these factors, color of the facial skin has been commonly used in practice as the basic reference for tooth shade selection [5-7].

Until recently, it was believed that people with fair skin color have brighter teeth while people with darker skin have darker teeth that are in harmony with the color of their skin [8]. However, recent studies have found conflicting results on the association between the natural skin color and tooth shade in different populations, with results ranging from no association to moderate association [9-12]. Hair and eye color has been shown to have minimal relation with tooth shade [12]. In light of these findings, the use of facial structures as a guide for shade selection has been discouraged, and the latest recommendations for tooth shade selection for complete mouth rehabilitation includes listening to the patient desires as the first and most important guide for shade selection [13, 14].

Different studies were conducted to investigate patients' perception of smile attractiveness.

Some studies have shown that generally individuals prefer whiter teeth regardless of their sex and socioeconomic status [1, 2, 4], while others identified age, gender, and the level of education as factors influencing patients' choice in tooth shade [1, 15, 16].

Two studies showed that the facial skin color influences people's perception of the attractiveness of tooth shades with different levels of value; people perceived the brightest teeth (teeth with highest value) in a fair skinned model as the most attractive and the darkest teeth (lowest value) in fair skinned model as the least attractive [17, 18]. These two studies present very interesting findings to build upon; however, they have digitally modified the tooth shade values without taking into consideration whether the shades used represent any of the tooth shade guides available in the clinic. Therefore, these results, although very useful, cannot be translated to clinical settings.

A more clinically applicable study was conducted in Saudi Arabia recently, which evaluated population preference of tooth shade using a commercially available A-D Shade guide to construct computer-modified images [19]. It showed that most of the study participants (83.7%) preferred lighter tooth shade for lighter skin shades, and darker tooth shade for darker skin [19]. However, the findings of this study cannot be generalized to other populations, since cultural and ethnical background could influence individuals' perception of smile attractiveness [20, 21]. To the best of our knowledge, there is no data regarding perception of esthetic tooth shades in North America.

Therefore, the objective of this study was to identify lay people's preference and the factors that could influence the preference for tooth shade for different skin shades, in a sample of North American populations.

6.4 Materials and methods

This study used a cross-sectional design and survey method. Ethical approvals were obtained from the Ethics Research Board of McGill University Health Center #13-406 and the University of the Pacific #16-117.

6.4.1 Data Collection

For data collection, two independent and subsequent online surveys were constructed and distributed using the SurveyMonkey online survey tool (SurveyMonkey, California, USA). Both surveys included a brief description of the study and an informed consent on the first page. The first of these surveys aimed at assessing people's preferred tooth shade characteristics (value, hue, and chroma) as a function of the skin shade of the perioral image. Building upon the preferred value, hue, and chroma identified in the first survey, a second independent survey was designed to pinpoint the most preferred tooth shade.

Although we aimed to get a convenient sample of laypeople with different ethnic, sociodemographic and educational backgrounds, we also wanted to include participants with dental affiliation for comparison. Therefore, the surveys were sent via email to the graduate students of the Faculty of Dentistry (both MSc and PhD, n = 40), McGill University, Montreal, Canada, and the students were asked to help distribute the links of the surveys to other groups. Additionally, links to the surveys were posted in social media groups of Montreal (Canada) and San Francisco (USA).

Both surveys consisted of an initial section to collect demographic data. Additionally, participant's perception of the importance of dental appearance and their level of satisfaction with their own smile were assessed using a visual analog scale from 0–10, in

which 10 represents highest importance or maximum satisfaction, respectively. The surveys also included the 14-plate Ishihara color blindness test [22]. Only participants with an Ishihara color blindness score of at least 11/14 were included in the analysis.

For the principal part of both surveys, a digital image representing the perioral area of a smile with a perfect set of teeth was constructed using Photoshop software (Adobe Photoshop CC, Adobe, California, USA) and was used as a model for the surveys. In addition, three questions were repeated at the end of each survey to evaluate the reliability.

The tooth shade and the skin shade of the model were selected from the VITA 3D-Master shade guide (Vita Zahnfabrik, Rauter GmbH and Co., Bad *Säckingen*, Germany) and Von Luschan's chromatic scale guide, respectively. The Von Luschan chromatic scale guide is a skin shade guide that consists of 6 categories of shades; each category contains 6 specific shades [23]. The shade tabs that were used in the questionnaires were chosen to represent the majority of available skin shades (#3 very light, #8 light, #13 intermediate light, #19 intermediate dark, #25 dark, and #32 very dark). Participants were asked to report on their own skin shade using a sample of these six skin shades.

The aim of the first survey was to assess people's preferred tooth shade characteristics (value, hue, and chroma) as a function of the skin shade of the study model. The principal part of this survey consisted of 18 questions organized in six sets of three questions each. Each set of three questions used models with one of the six skin shades selected for this study. Moreover, the first question in each set of three questions used models with different tooth shade values (2M1, 3M1, 4M1); the second questions used models with different tooth shade hues (3L1.5, 3M1, 3R1.5); and the third question used models with different tooth shade chromas (3M1, 3M2, 3M3) (Figure 6.1).

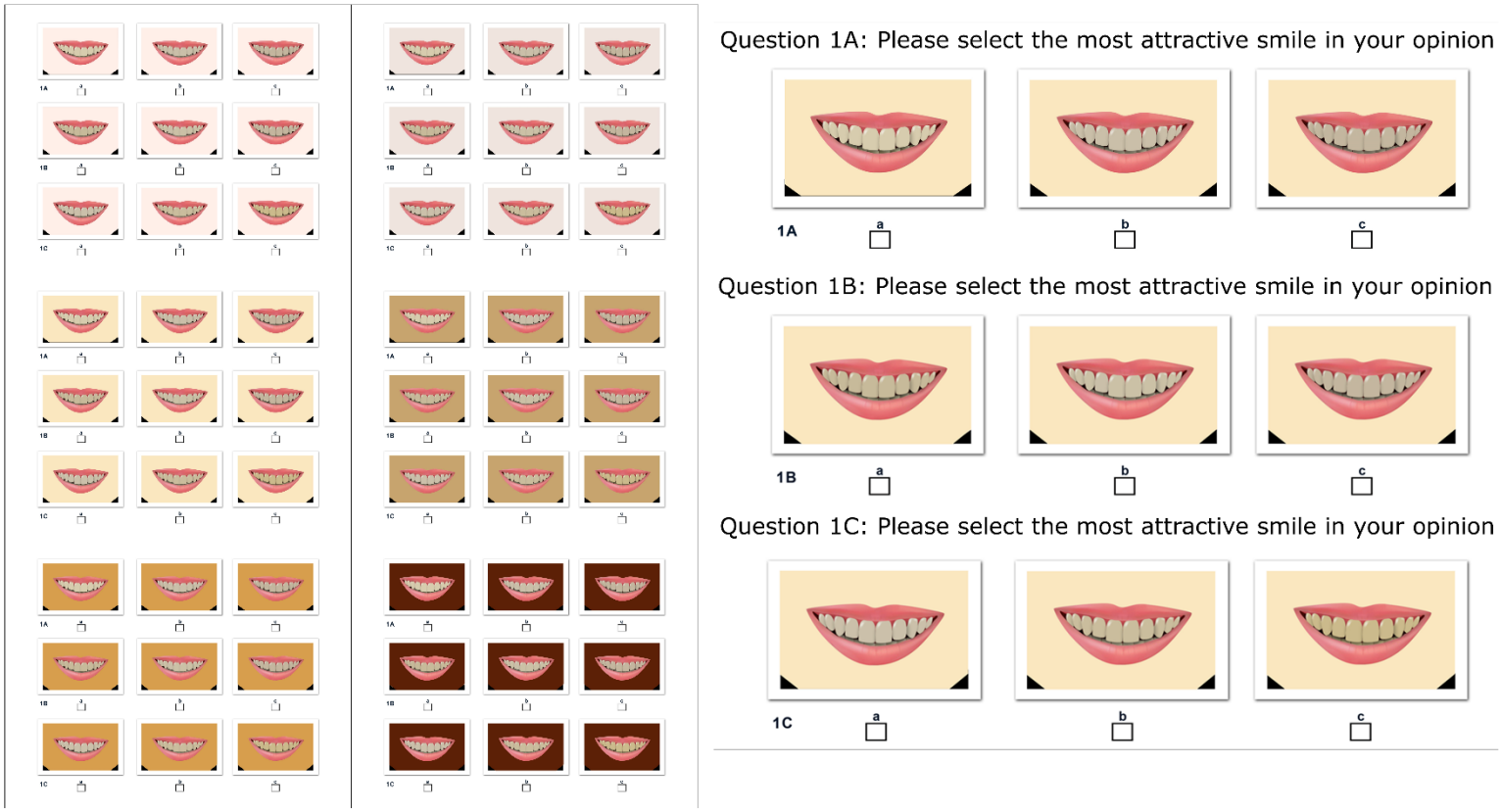


Figure 6.1: Questions of the first survey. Left side: the 6 sets of three questions each comprising second part of survey 1. Right side: an example of one set of questions for skin shade of intermediate light #13. From left to right, the first question shows teeth with three different values 2M1, 3M1, 4M1, the second question shows three different hue 3L1.5, 3M1, 3R1.5, and the third question represents three different chromas 3M1, 3M2, 3M3.

For each question of the survey, participants were asked to choose the most attractive model in their opinion out of the three models displayed by digitally checking a checkbox under the model of choice. This type of questions is called three-alternatives forced choice question. A single answer was accepted for each question.

The second survey was designed based on the results obtained from the first survey. For the principal part of the second survey, the most preferred tooth shade characteristics, identified in the first survey (value, hue, chroma), were utilized to identify the most preferred tooth shades in the VITA 3D-Master shade guide. The survey consisted of six questions. Each question consisted of 4 perioral images with the same skin shade but with a different tooth shade for each image; 1M1, 2M1, 3M1, and 4M1. Each of the six questions used one of the six skin shades used in the first survey (Figure 6.2).

The second survey was designed based on the results obtained from the first survey. For the principal part of the second survey, the most preferred tooth shade characteristics, identified in the first survey (value, hue, chroma), were utilized to identify the most preferred tooth shades in the VITA 3D-Master shade guide. The survey consisted of six questions. Each question consisted of 4 perioral images with the same skin shade but with a different tooth shade for each image; 1M1, 2M1, 3M1, and 4M1. Each of the six questions used one of the six skin shades used in the first survey (Figure 6.2). This resulted in a total of six questions in the survey, one for each skin shade.

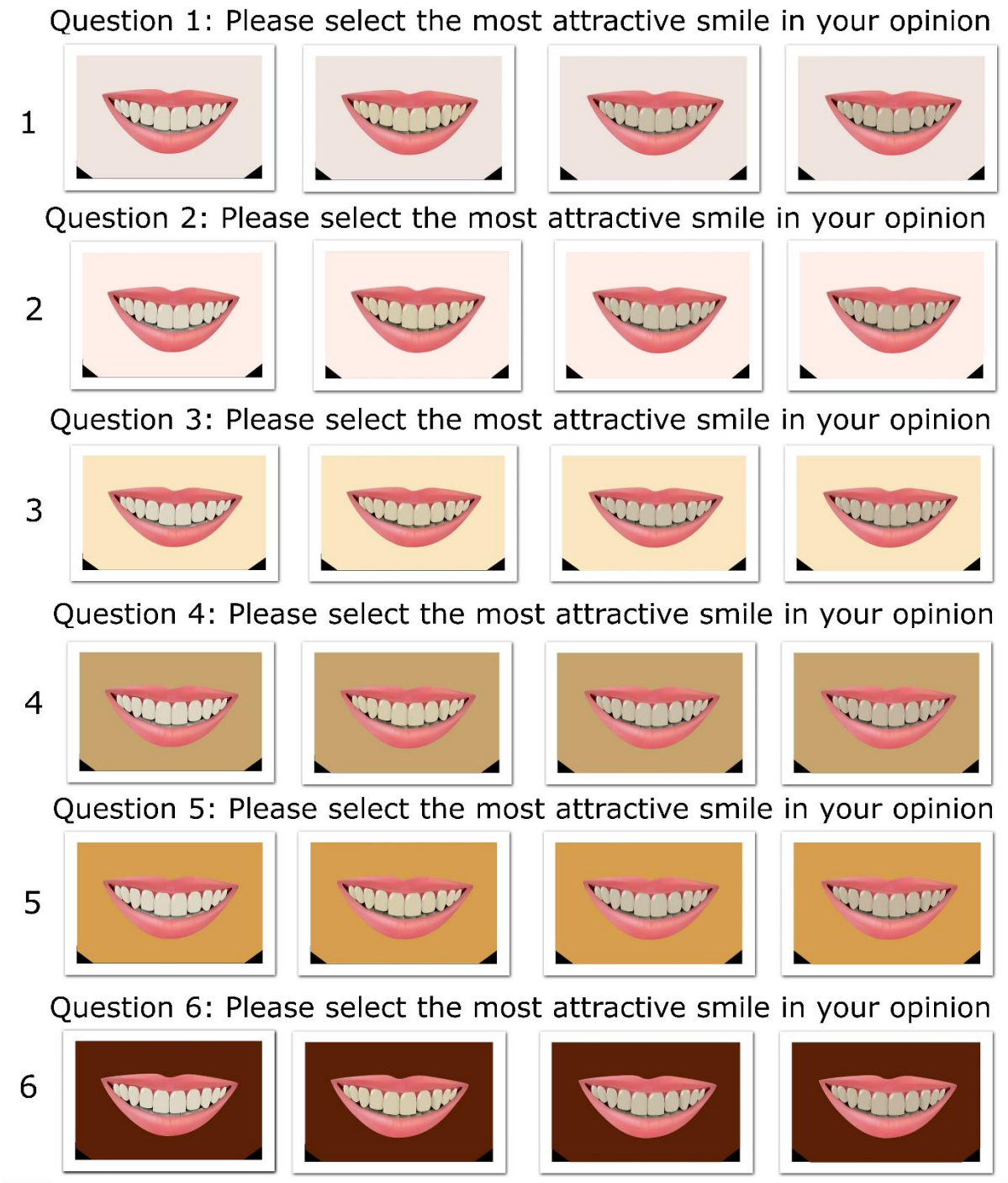


Figure 6.2: Second survey shows six questions. Each question includes 4 models with identical Von Luschan skin shade (1): very light #3, (2): light #8, (3): intermediate light #13, (4): intermediate dark #19, (5): dark #25, (6): very dark #32, and different tooth shades (from left to right: 1M1, 2M1, 3M1, 4M1)

6.4.2 Statistical Analysis

Descriptive statistics and univariate analysis were used to examine the frequency distribution of the data. We used Chi-Square goodness of fit non-parametric test to compare the observed sample distribution with the expected probability distribution in regard to participant preference of different values, hues, and chromas for each skin shade.

People's preferences regarding tooth shade values, hues, or chromas across different skin shades of the model were analyzed using a mixed-effects models to account for the repeated measurements. Mixed-effects ordinal logistic regression model was used to analyze people's preference regarding tooth shade value and chroma, in addition to people's preference regarding tooth shades in the second survey, as these outcomes were coded on an ordinal scale. On the other side, a multinomial logistic regression model was used to analyze people's preference of hue, as hue is a nominal variable. All models were adjusted for the following potential confounders: skin shade of the model, age, gender, level of education, dental affiliation, participants' satisfaction with their smile, and their perception of the importance of the smile. Weighted Cohen Kappa was used to assess the reliability of participants answers of repeated questions in the surveys [27]. P-value < 0.05 was considered statistically significant. Data was analyzed using STATA 14 software package (StataCorp LCC, Texas, USA).

6.5 Results

6.5.1 First survey: people preference of tooth shade characteristics (value, hue, chroma)

From a total of 154 returned questionnaires in the first survey, 34 questionnaires were excluded because they either failed the color blindness test or did not answer any question

in the surveys. Most of the participants in the first survey were female (65.8%), younger than 35 years old (79.9%), without dental affiliation (59.2%), and had postsecondary education (79.1%), Table 6.1.

Table 6.1: Demographic Characteristics of the included participants in the first and second survey

	First survey (n=120)	Second survey (n=70)
Participants n. (%)		
Age		
18-25	22 (18.3%)	14 (20%)
26-34	74 (61.6%)	40 (57.1%)
35-44	10 (8.3%)	7 (10%)
45 and older	14 (11.6%)	7 (10%)
Sex		
Male	41 (34.16%)	30 (42.85%)
Female	79 (65.8%)	40 (57.1%)
Skin shade of participants		
Very light	9 (7.5%)	3 (4.2%)
Light	27 (22.5%)	10 (14.2%)
Intermediate light	22 (18.3%)	16 (22.8%)
Intermediate dark	44 (36.6%)	35 (50%)
Dark	13 (10.8%)	2 (2.8%)
Very dark	1 (0.008%)	0 (0%)
Dental affiliation		
Yes	49 (40.8%)	28 (40%)
No	71 (59.2%)	42 (60%)
Education		
Secondary	25 (20.8%)	10 (14.3%)
Post-secondary	95 (79.1%)	60 (85%)
Excluded participants		
Failed color blindness	6 (3.8%)	4 (5.3%)
Left questionnaire without answers	28 (18.18%)	1 (1.3%)
Total	34 (22.07%)	5 (6.6%)

6.5.1.1 Preferred value, hue and chroma

In general, most of the participants preferred the highest value (54.59%), neutral hue (59.18%), and the lowest chroma (88.52%) regardless of skin shade of the model (Table S6.1 and Figures 6.3 and 6.4) with one exception, the intermediate value was the most preferred value in models with very dark skin shade (47.69%).

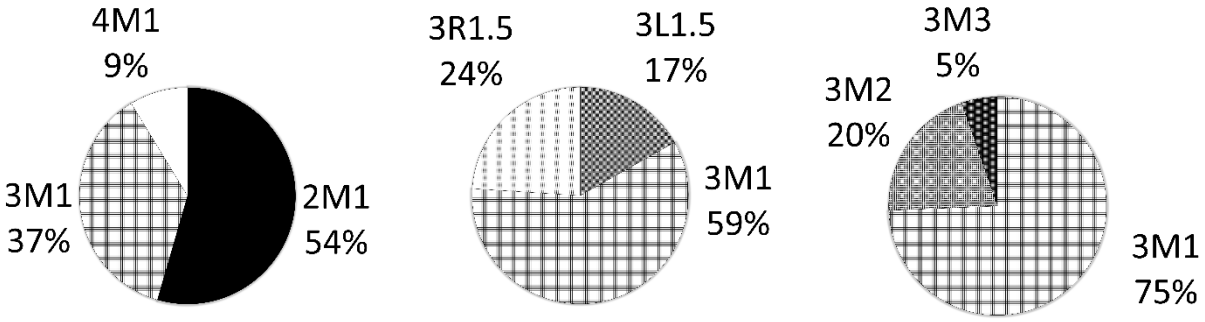
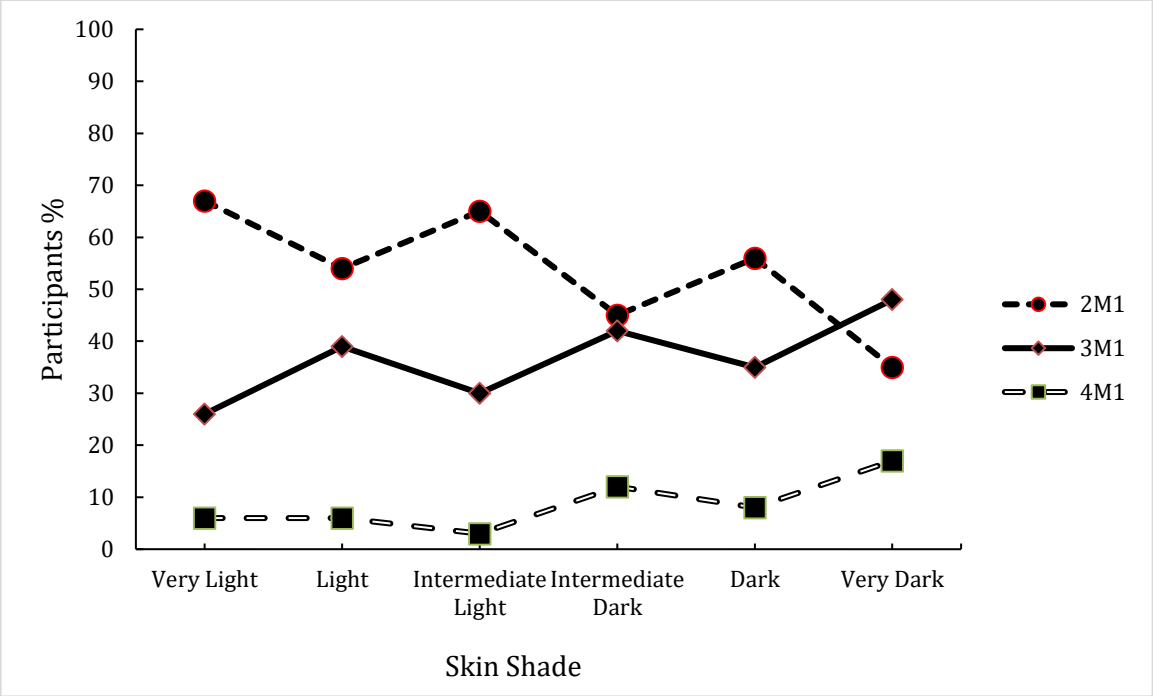


Figure 6.3: Results of the first survey: Percentage of people preference of value (left), hue (center) and chroma (right)

Table 6.2: Results of the first survey: Preferred tooth shade value, hue and chroma in models with different skin shades

Skin shade of the model	**Participants %**											
	Tooth shade value			P value	Tooth shade hue			P value	Tooth shade chroma			P value
	2M1	3M1	4M1		3L1.5	3M1	3R1.5		3M1	3M2	3M3	
Very light	67.2*	26	6.7	<.001	22.2	64*	13.6	<.001	92*	7.6	0	<.001
Light	54.7*	39.3	5.9	<.001	9.4	64.9*	25.6	<.001	91*	6.8	1.7	<.001
Intermediate light	64.9*	31.5	3.5	<.001	12	67.6*	20.3	<.001	90.9*	6.3	2.7	<.001
Intermediate dark	45.7*	42	12.1	<.001	20.5	57.9*	21.5	<.001	86*	12	1.8	<.001
Dark	56*	35.5	8.4	<.001	22.4	53.3*	24.3	<.001	86.6*	11.4	1.9	<.001
Very dark	35.3	48*	16.6	<.001	14.5	45.6*	39.8	<.001	82.8*	16.2	0.9	<.001

*denotes statistical significance among the horizontal line using Chi-square goodness of fit test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Participants %
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Intermediate Light
Intermediate Dark
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Very Dark
Skin Shade
2M1
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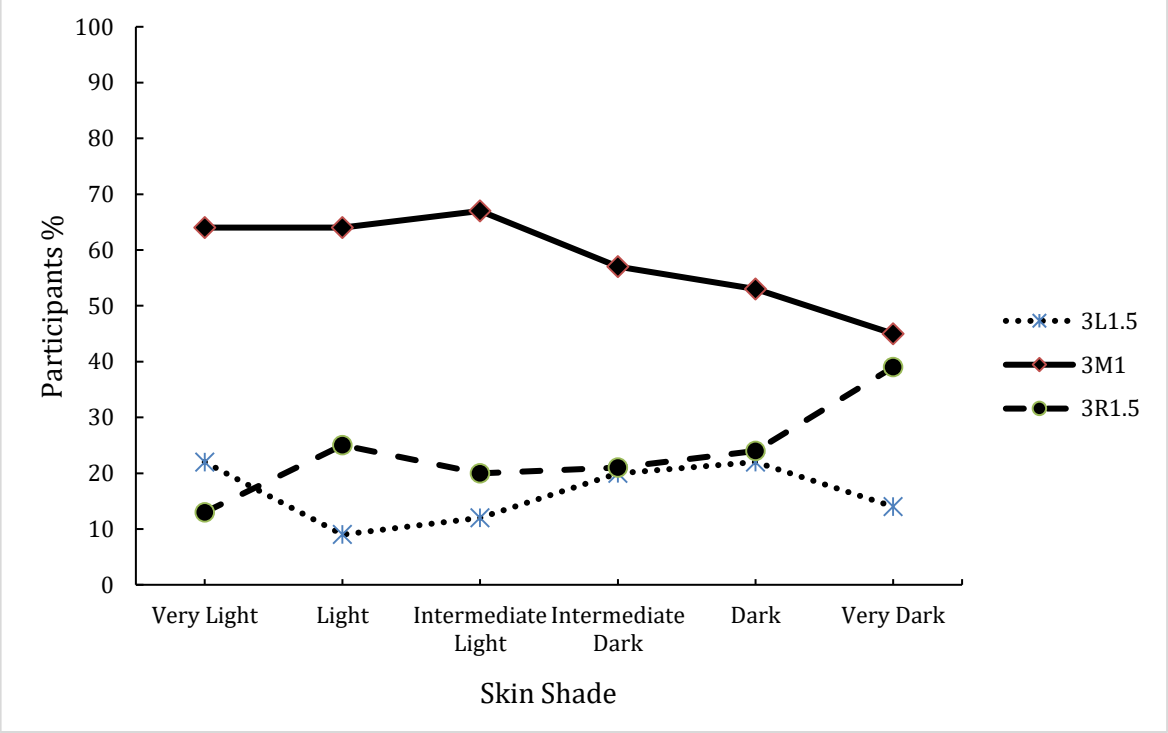
100
90
80
70
60
50
40
30
20
10
0
Participants %
Very Light
Light
Intermediate Light
Intermediate Dark
Dark
Very Dark
Skin Shade
3L1.5
3M1
3R1.5

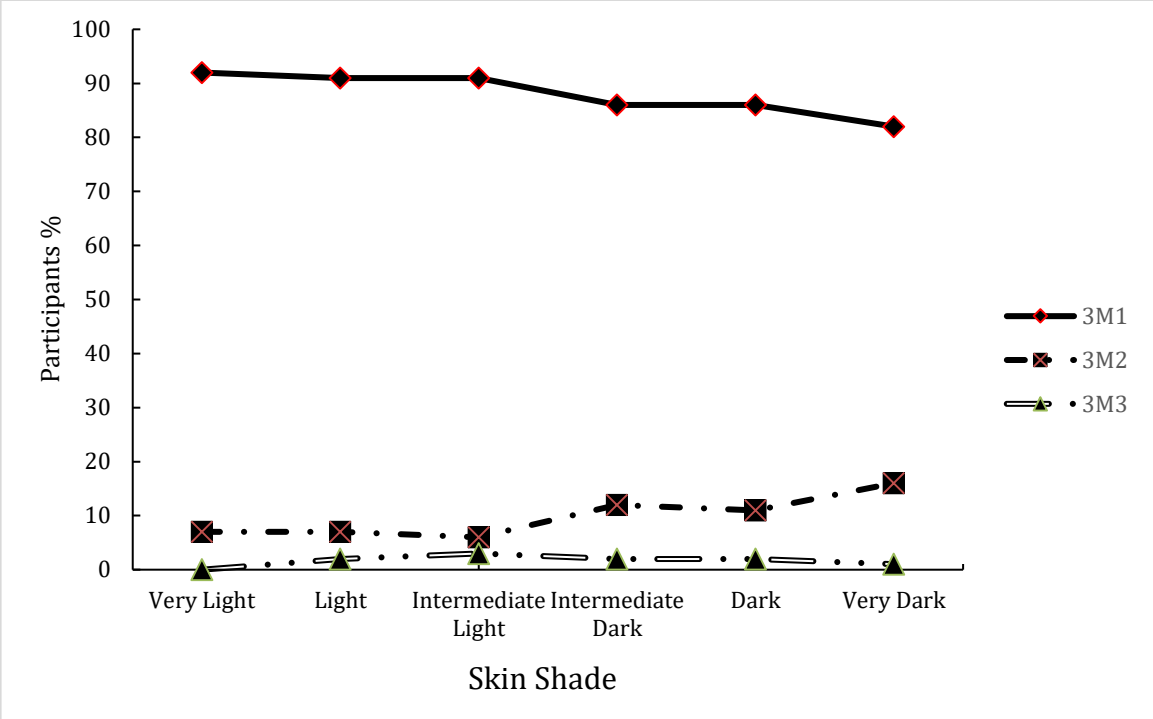

Figure 6.4: Results of the first survey: people preference of different value (the top), hue (the middle) and chroma (the bottom) as a function of skin shade of the model

Among the observer-related variables assessed (age, sex, level of education, dental affiliation, perception of the importance of dental appearance and of satisfaction with participant's own smile), only the dental affiliation of the observer was significantly associated with preference of tooth shade value (p-value = 0.047). Dentally affiliated participants were significantly less likely to prefer high value tooth shades compared with non-dental professionals (OR= 0.88, 95% CI: 0.79-0.99) (Table 6.2). None of the observer-related variables showed significant association with people's preference of hue or chroma (p-value > .05), (Tables S6.2 and S6.3).

6.5.1.2 Reliability in the first survey

Weighted kappa score for reliability was 0.46 ± 0.06 (SE: standard error), which indicates a moderate level of agreement [25].

Table 6.3: Results of first survey: Influence of observer-related variables on people preference of tooth shade value

Variable	Participants (n) Preferred value			Odds Ratio** (95% CI)	P value
	High	medium	low		
Gender					
Male	130	85	14	1	--
Female	233	159	44	0.71 (0.34-1.48)	0.375
Education					
Secondary	80	44	9	1	--
Postsecondary	282	200	49	0.67 (0.38-1.19)	0.176
Age					
<25	74	43	6	1	--
25-34	208	151	42	0.75 (0.29-1.49)	0.561
35-44	33	25	2	0.99 (0.24-4.0)	0.994
>45	48	25	8	0.81 (0.22-2.95)	0.752
Dental affiliation					
No	234	127	36	1	--
Yes	129	117	22	0.88 (0.79-0.99)	0.047*

*statistically significant at $p<0.05$

** Odd ratio of preferring high value over medium and low value from mixed-effects ordinal logistic regression

6.5.2 Results of the second survey: the preferred tooth shade

For the second survey, a total of 70 questionnaires were included. Most of the participants

were female (57.2%), younger than 35 years old (77.1%), without dental affiliation (60%), and had postsecondary education (85%), (Table 6.1). Most of the participants preferred 1M1 (75%), followed by 2M1 (15%), and the least preferred shade was 4M1(3%), regardless of the skin shade of the model (Figures 6.5 and 6.6, table S6.4).

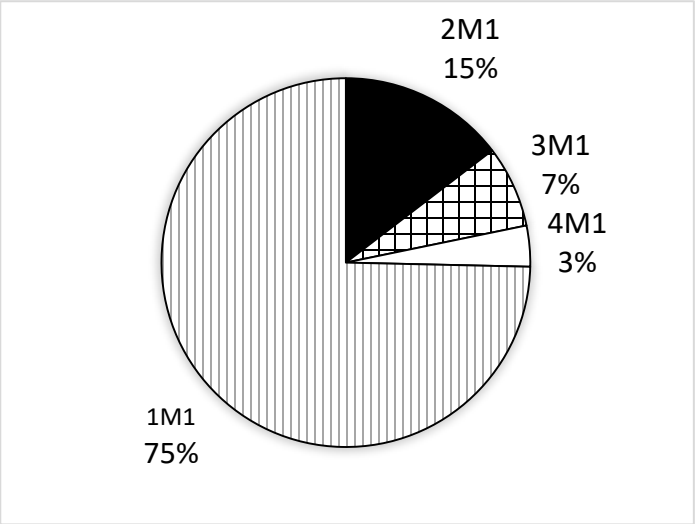

Figure 6.5: Results of the second survey: Percentage of people preference of tooth shade

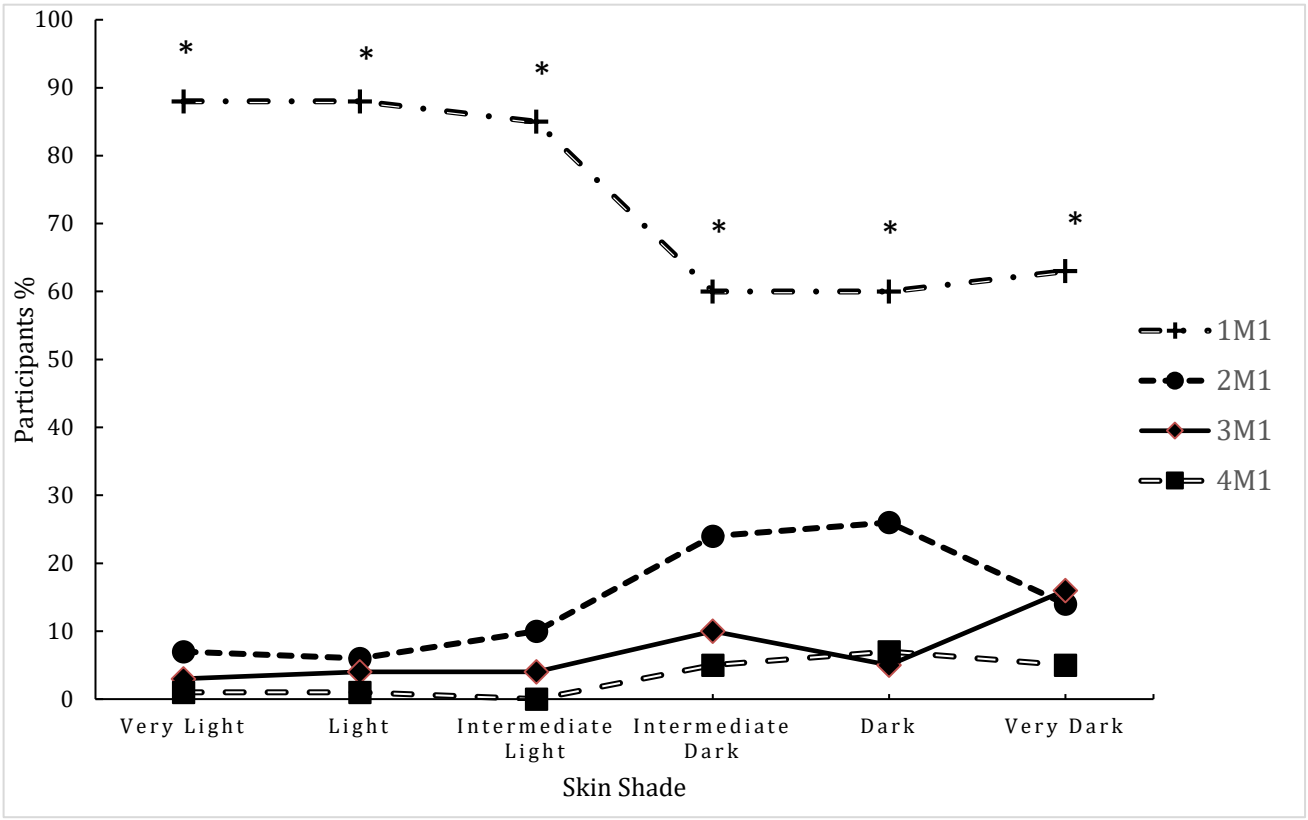

Figure 6.6: Results of the second survey: people preference of different tooth shades as a function of skin shade of the model

* indicates statistical significant difference compared to other tooth shades in each skin shade

Table 6.4: Results of second Survey: Preferred tooth shade in models with different skin shade

Tooth shade	**Participant n (%) Skin shade of the model**					
	Very light	Light	Intermediate light	Intermediate dark	Dark	Very dark
1M1	62 (88.5)*	62 (88.5)*	60 (85.7)*	42 (60)*	42 (60)*	44 (62.8)*
2M1	5 (7.2)	4 (5.7)	7 (10)	17 (24.3)	18 (25.7)	10 (14.3)
3M1	2 (2.8)	3 (4.3)	3 (4.3)	7 (10)	4 (5.7)	11 (15.7)
4M1	1 (1.5)	1 (1.5)	0 (0)	4 (5.7)	5 (7.3)	4 (5.7)
P value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

*denotes statistical significance in the vertical column using Chi-square goodness of fit test

People's preference of tooth shade were significantly associated with both age of participants (p=0.019) and their satisfaction with their own smile (p-value = 0.005), (Table 6.5). Participants younger than 25 years and participants with higher satisfaction with their own smiles were significantly more likely to prefer light tooth shade (1M1) compared with participants older than 45 years.

Table 6.5: Results of second survey: influence of observer-related variables on people preference of tooth shade

Variable	Preferred Shade No. of participants				Odds Ratio* (95% CI)	P value
	1M1	2M1	3M1	4M1		
Gender						
Male	115	26	13	6	1	--
Female	183	31	17	9	0.74 (0.18-2.94)	0.664
Age						
<25	66	11	3	4	1	--
25-34	189	23	17	9	0.46 (0.07-3.03)	0.422
35-44	26	11	5	0	0.16 (0.01-2.15)	0.170
>45	19	16	5	2	0.03 (0.01-0.59)	0.019**
Education						
Secondary	33	7	6	2	1	--
Postsecondary	267	54	24	13	1.07 (0.35-3.12)	0.898
Dental affiliation						
No	189	32	21	8	1	--
Yes	123	29	9	7	1.02 (0.81-1.30)	0.817

*odds of preferring higher values over lower values using mixed-effects ordinal logistic regression

**statistically significant at 0.05

6.5.2.3 Reliability for the second survey

Weighted kappa score for the reliability on preferred tooth shade was 0.72 ± 0.09 (SE), which indicates a substantial level of agreement [25].

6.6 Discussion

Patient's perception of smile esthetics is a very important factor to be considered during designing esthetic restorations. To the best of our knowledge, this is the first study to identify tooth shade preferences as a function of facial skin shade in a North American study sample. This study revealed that the most preferred tooth shade for anterior teeth is 1M1 in the 3D Master shade guide, which is equivalent to B1 in the Classic VITA shade guide [26], regardless of the skin shade of the model and their demographic variables. The CIE average values for L, a and b for 1M1 shade tab were measured in a previous study to be around 86.4 (1.0), -0.4 (0.1), and 10.7 (0.3), respectively.

Standards of beauty have been discussed in the social sciences for some time. A common notion is that "beauty is in the eye of the beholder," which indicates that beauty standards may reflect cultural conventions [27]. However, recent research has pointed out that people's views of facial attractiveness are quite consistent regardless of ethnicity, age, or nationality. Psychologists believe that biological reasons are behind this as it seems that people look for signs of health as attractive traits for their partners. For example, smooth single blend skin shade is the most preferred skin trait for facial attractiveness, which could be related to the fact that the condition of skin surface can indicate the quality of the immune system [28].

Although the smile and tooth color are important traits to determine facial attractiveness, related research in the dental field is still scarce [29]. In an attempt to understand why North American people like straight white teeth, a study demonstrated that dental esthetic tendencies are biologically, culturally, and socially patterned [30]. White teeth have symbolically represented youth and good health [30].

This study demonstrated people's preference for the whitest teeth, in two cities in North America, which confirms previous literature on people's preference for the whitest teeth [1, 2, 4]. This fixation on white teeth could stem from the fact that beauty represents health and youthfulness [28]. In fact, white teeth are associated with small-sized enamel crystals [31], which were in turn also associated with signs of health and optimal function such as higher hardness and toughness [32].

Very few studies reported that whitest teeth were not perceived as the most attractive [15, 33]. However, one of these studies used written statements without photographs [15] and the other used full face photographs [33]. Using statements without photograph is not precise as people understanding of statements could vary [20]. Full face photographs introduce many confounding variables that bias the results [34].

Most participants in our study preferred the whitest tooth shade in all models regardless of the skin shade of the model. This came in disagreement with previous studies that reported that while most of the participants preferred the whitest teeth in fair skin shades, in dark skin shades the less white tooth shades were the most preferred [17-19]. This difference could be related to the range of tooth shades used in the previous studies; we used tooth shades from the VITA 3D-Master shade guide which represent shades commonly seen in natural teeth, but previous studies used a bleached tooth shade guide or artificially whitened

tooth shades in addition to the natural tooth shades [17-19].

This study showed that people's age and dental affiliation were significant predictors of their preferred tooth shade which came in agreement with previous studies [15, 17, 18, 20, 21, 35]. Similar studies have identified that dentists and patients have different perception of smile attractiveness. This is probably due to the way dentists are trained in dental schools to choose darker shades for patients with darker skin shades [6, 7]. Therefore, patient participation in treatment decision making process is recommended [21].

Most of the tooth shade studies in the literature did not report reliability scores [1, 18-20, 36, 37]. In this study, reliability score of people preferences of tooth shade characteristics in the first survey (kappa score 0.46± 0.06) indicated moderate level of agreement and it confirms the reported limited reproducibility of visual shade matching technique [38], which should be taken into consideration when evaluating reliability scores of tooth shade studies [39].

In their study, Sabherwal et al. reported higher reliability score range of (0.57-0.76) in participants' preferences of tooth shade value compared to our first survey, and that could be related to the fact that in their study half of the participants were dentists [17]. Moreover, our kappa scores are still in the range of reliability scores reported in the literature of studies using computer-modified images [40, 41]. Additionally, our results of the second survey scored a substantial high reliability (0.72±0.09) and confirmed results of the first survey.

This study has several points of strength. It utilized one of the most commonly used shade guides in practice, thus allowing easy translation into clinical practice. Using digitally-modified perioral images had the advantage of eliminating confounding facial beauty on

participants' rating of attractiveness [20]. On the other hand, this study has few limitations including the sampling technique; the majority of the participants included were educated young females, which limits the generalizability of the results. To overcome this limitation, further studies are recommended with random sampling techniques to include a more diverse population. Nevertheless, this study has provided initial vital data on the topic.

6.7 Conclusions

The lightest tooth shade (1M1 in 3D Master, which is equivalent to B1 in the VITA Classic shade guide) was considered the most attractive tooth shade by most participants regardless of perioral skin color, and observer-related variables.

6.8 Acknowledgement

The authors would like to acknowledge the support provided by the Society of Color and Appearance in Dentistry Award, 2014. The authors would also like to thank Dr. Jose Correa (Statistician, McGill University) for his valuable statistical advice and Ms. Jenelen Cordovez (Photographer, King Saud University) for her valuable help constructing the survey images.

6.9 Supplementary information

Table S6.1: The effect of skin shade of the model on the participants preference of tooth shade characteristics (top: value, mid: hue, bottom: chroma)

	Skin shade of the model					
	Very light	Light	Intermediate light	Intermediate dark	Dark	Very dark
Tooth shade value						
2M1	80	64	74	49	60	36
3M1	31	46	36	45	38	49
4M1	8	7	4	13	9	17
OR	1	0.52	0.98	0.28	0.53	0.17
P value	----	0.038*	0.955	<0.001*	0.054	<0.001*
95% CI	----	(0.28, 0.96)	(0.52, 1.85)	(0.15, 0.53)	(0.28, 1.10)	(0.09, 0.32)
Tooth shade hue						
3L1.5	26	11	13	22	24	15
3M1	75	76	73	62	57	47
3R1.5	16	30	22	23	26	41
OR	1	1.02	1.10	0.71	0.60	0.44
P value	----	0.917	0.697	0.206	0.056	0.005*
95% CI	----	(0.63, 1.66)	(0.65, 1.86)	(0.43,1.19)	(0.35,1.01)	(0.25, 0.78)
Tooth shade chroma						
3M1	109	106	100	93	91	87
3M2	9	8	7	13	12	17
3M2	0	2	3	2	2	1
OR	1	0.63	0.66	0.34	0.35	0.24
P value	----	0.420	0.475	0.047*	0.059	0.008*
95% CI	----	(0.21, 1.91)	(0.21, 2.06)	(0.12, 0.98)	(0.12, 1.04)	(0.08, 0.69)

*statistically significant at $p<0.05$ using mixed-effects ordinal logistic regression

OR: odds ratio

Table S6.2: Influence of observer-related variables on people preference of tooth shade hue

Variable	No. of participants Preferred hue			Odds Ratio*	P value	95% Confidence interval	
	3L1.5	3M1	3R1.5			low	upper
Gender							
Male	37	138	50	1	--	--	--
Female	74	252	108	1.18	0.614	0.61	2.32
Education							
Below university	22	81	31	1	--	--	--
University	88	309	127	0.77	0.278	0.48	1.23
Age							
<25	23	73	27	1	--	--	--
25-34	69	224	101	1.18	0.728	0.46	3.02
35-44	3	48	9	3.96	0.055	0.99	1.57
>45	16	45	21	0.97	0.971	0.32	2.95
Dental affiliation							
No	64	228	97	1	--	--	--
Yes	47	162	61	0.97	0.647	0.87	1.08

* Odds ratios of preferring 3M1 over 3L1.5 calculated from multinomial regression model

Variable	No. of participants Preferred hue			Odds Ratio*	P value	95% Confidence interval	
	3L1.5	3M1	3R1.5			low	Upper
Gender							
Male	37	138	50	1	--	--	--
Female	74	252	108	0.87	0.610	0.53	1.44
Education							
Below university	22	81	31	1	--	--	--
University	88	309	127	0.73	0.080	0.51	1.03
Age							
<25	23	73	27	1	--	--	--
25-34	69	224	101	1.06	0.840	0.59	1.90
35-44	3	48	9	3.35	0.119	1.22	9.21
>45	16	45	21	0.86	0.725	0.39	1.89
Dental affiliation							
No	64	228	97	1	--	--	--
Yes	47	162	61	0.98	0.762	0.91	1.06

* Odds ratios of preferring 3M1 over 3R1.5 calculated from multinomial regression model

Table S6.3: Influence of observer-related variables on people preference of tooth shade chroma

Variable	Preferred chroma No. of participants			Odds Ratio*	P value	95% Confidence interval	
	Low	medium	High			low	Upper
Gender							
Male	209	18	1	1	--	--	--
Female	377	48	9	0.52	0.253	0.16	1.59
Level of education							
Below university	119	8	3	1	--	--	--
University	466	58	7	0.60	0.240	0.25	1.40
Age							
<25	107	12	3	1	--	--	--
25-34	362	31	5	1.88	0.355	0.49	7.10
35-44	58	2	0	5.14	0.174	0.48	5.62
>45	59	21	2	0.33	0.198	0.06	1.79
Dental affiliation							
No							
Yes	352	38	6	1	--	--	--
	234	28	4	0.96	0.727	0.81	1.15

*Odds ratios calculated from mixed-effects ordinal logistic regression

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Chapter Seven
Discussion

7.1 **Discussion of the results**

This thesis assessed the association between three denture-related variables (denture base, fabrication technique and artificial tooth shade) and patient-reported outcomes for removable partial denture treatments. Below we discuss the key findings of the thesis.

7.1.1 Denture base

The results of our systematic review showed that only weak evidence exists on the effect of denture base on patient-reported outcomes. The pooled effect size of patient satisfaction and oral health-related quality of life showed no statistical significant difference between acrylic resin and metal RPDs. On the other side, patient compliance was significantly higher in metal compared to acrylic resin RPDs groups. However, most of the included studies had low level of evidence, cross-sectional study design and serious risk of bias.

This is the first review to synthesize the evidence in this topic. Comparing the pooled effect size in oral health related quality of life and patient satisfaction with minimum important difference reported in the literature indicated that the results of this review is inconclusive and further studies are needed to answer the review question. This review also indicated the main study design issues that need to be considered when designing new studies in this topic.

7.1.2 Denture fabrication technique

The results of our pilot clinical trial showed that laser-sintered removable partial dentures scored significantly higher patients satisfaction compared to traditional cast RPDs. It also showed that laser-sintered RPDs were associated with fewer complaints and more compliments compared to the cast RPDs. Finally, laser-sintered removable partial dentures were preferred over the traditional cast RPDs. Our results supported previous studies in restorative dentistry that showed the promising results on the fitting accuracy of restorations fabricated using the laser-sintering technique [148-150]. It is expected that fitting accuracy have impacted the patient perceptions of RPD positively as it is shown in the results of this study.

7.1.3 Tooth shade

Our results showed that the most preferred tooth shades were the shades with highest value, neutral hue and lowest chroma. The most preferred tooth shade among the general public was 1M1 in VITA 3D-Master Shade guide, which is equivalent to B1 in VITA Classical Shade guide. Regarding the effect of skin shade, people preferred 1M1 regardless of the skin shade of the model. These results confirmed the previous literature on people preference of the highest value or the whitest tooth shade. It also supports the current clinical recommendation in shade selection which discourages using the facial skin shade as a guide.

7.2 **Limitations**

7.2.1 generalizability

There are several limitations that limit the generalizability of the results of this thesis. First, our clinical trial had a small sample size and a short follow-up time. Additionally, the results of clinical trials in general has limited generalizability to everyday practice due to the strict inclusion criteria. To provide more generalizable results, pragmatic studies are recommended.

Another limitation to the generalizability of the results of this thesis is related to the sampling technique used in our cross sectional survey study. A convenient snowball sampling resulted in a sample of mostly young educated female participants, which limits the generalizability of the study results.

7.2.2 Internal validity

The measures used in this thesis were self-reported, making the results more susceptible to recall bias and response style effect, which is the participants tendency to select extreme ratings on a scale. Additionally, participants preferences and social desirability might have affected the responses. These are inherent sources of biases in self-reported measures of patient-reported outcomes.

Another limitation to the internal validity is related to the use of online surveys of computer-modified images. Images might looked different in different screens, which could resulted in nuisances and affected the effect size.

7.3 Clinical Significance

The findings of this thesis explained the effect of several denture-related variables on patient-reported outcomes of removable partial dentures, and could be used by dentists to

improve the quality of treatment provided to their patients. Choosing a promising fabrication technique, and using laypeople preferred tooth shades as a guide could help provide a more successful treatment from patients' perspectives.

Additionally this thesis has shed light on the possible denture-related variables that could be further studied to improve the quality of removable partial dentures. It indicated the lack of good evidence on the effect of denture base materials on patient-reported outcomes, which is an important clinical question for everyday practice.

7.4 Recommendations and future directions

To overcome the limitations of the present studies, randomized controlled clinical trials with larger sample size and longer follow-up time to explore the relationship between the RPD fabrication techniques and the patient-reported outcomes. Additionally, economic evaluation of the different RPD fabrication techniques both on the short and long-term is recommended to aid clinicians and patients on treatment planning and decision making, respectively.

Moreover, a random representative sample of North American population is recommended to confirm the results of the most preferred tooth shade among the general public. Future work towards exploring the effect of cultural differences on people preferred tooth shade as a function of the skin shade in different populations is recommended.

Chapter Eight

Conclusions

The global conclusion of this thesis is that denture fabrication technique has an effect on patient-reported outcomes of RPD treatment while the effect of denture base material was unclear in the literature.

Within the limitations of this thesis, the following conclusions can be drawn:

1. Our systematic review found that only low evidence exists on patients-reported outcomes concerning metal and acrylic resin RPDs, and it showed that there was no significant difference between metal and acrylic resin RPDs in terms of patient satisfaction and oral health-related quality of life.
2. The use of laser-sintering technology for the fabrication of removable partial dentures may lead to higher short-term satisfaction for patients with partial edentulism when compared with traditional methods.
3. Our survey showed that most participants preferred tooth shades with the highest value, neutral hue and lowest chroma. The lightest tooth shade (1M1 in VITA 3D-Master which is equivalent to B1 in VITA Classical shade guide) was considered the most attractive tooth shade by most participants regardless of perioral skin color.

Chapter Nine

Bibliography

Note: this is the bibliography of chapters one, two, three, seven and eight.

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Appendices

Appendix I: McGill Denture Satisfaction Questionnaire

VAS PRATIQUE QUESTIONNAIRE

Nom de famille: Prénom:

Date: / / **Phase I** **Phase II**

y y m m d d

Nous aimerions savoir si vous avez une bonne compréhension de la façon de répondre à ce questionnaire, qui utilise des échelles linéaires. S'il vous plaît placer un repère vertical à travers la ligne horizontale dans le lieu qui représente le mieux le nombre écrit sur la gauche, comme dans l'exemple suivant:

Exemple :

50% 0 _____ 100

25%	0 _____ 100	1. ☐☐☐
80%	0 _____ 100	2. ☐☐☐
10%	0 _____ 100	3. ☐☐☐
45%	0 _____ 100	4. ☐☐☐
75%	0 _____ 100	5. ☐☐☐

ÉVALUATION DE PROTHESE

Nom de famille: Prénom:

Date: / / **Phase I** **Phase II**

Y y m m d d ○ ○

Nous aimerions savoir comment vous êtes satisfait de votre prothèse présente. Lire chacune des questions suivantes et tracez une ligne verticale sur la ligne horizontale, où vous pensez que votre réponse correspond le mieux. Dans le cas où une question ne se applique pas à vous, par exemple, si vous ne mangez pas un certain type de nourriture, écrivez une brève explication sur la ligne.

1. Facilité de nettoyage
S'il vous plaît indiquer combien il est difficile de nettoyer votre prothèse et la bouche

extrêmement difficile _____ Pas du tout difficile 1. □□□

2. satisfaction générale
En général, êtes-vous satisfait de votre prothèse?

Pas du tout satisfait _____ extrêmement satisfait 2. □□□

3. Capacité de parler
S'il vous plaît indiquer combien il est difficile pour vous de parler à cause de votre prothèse?

extrêmement difficile _____ Pas du tout difficile 3. □□□

4. Le Confort
Êtes-vous satisfait du confort de votre prothèse?

Pas du tout satisfait _____ extrêmement satisfait 4. □□□

5. Esthétique
Êtes-vous satisfait de l'apparence de votre prothèse?

Pas du tout satisfait _____ extrêmement satisfait 5. □□□

6. Conservation et la stabilité

Êtes-vous satisfait de la rétention (étanchéité) de votre prothèse? 6. ☐☐☐

Pas du tout satisfait _____ extrêmement satisfait

Êtes-vous satisfait de la facilité de supprimer votre prothèse? 7. ☐☐☐

Pas du tout satisfait _____ extrêmement satisfait

Est-ce que vos rochers de prothèse avant et en arrière dans votre bouche quand vous mâchez? 8. ☐☐☐

Tout le temps _____ Jamais

Pensez-vous que votre prothèse sort facilement lors de la mastication? 9. ☐☐☐

Tout le temps _____ Jamais

Pensez-vous que votre prothèse sort facilement en parlant? 10. ☐☐☐

Tout le temps _____ Jamais

Pensez-vous que votre prothèse sort facilement avec votre langue? 11. ☐☐☐

Tout le temps _____ Jamais

7. Capacité à mâcher

En général, ne trouvez-vous difficile à mâcher la nourriture en raison de votre prothèse? 12. ☐☐☐

extrêmement difficile _____ Pas du tout difficile

S'il vous plaît indiquer combien il est difficile pour vous de manger du pain blanc frais à cause de votre prothèse? 13. ☐☐☐

extrêmement difficile _____ Pas du tout difficile

S'il vous plaît indiquer combien il est difficile pour vous de manger du fromage à pâte dure à cause de votre prothèse? 14. ☐☐☐

extrêmement difficile _____ Pas du tout difficile	
S'il vous plaît indiquer combien il est difficile pour vous de manger des carottes crues en raison de votre prothèse?	15. ☐☐☐
extrêmement difficile _____ Pas du tout difficile	
S'il vous plaît indiquer combien il est difficile pour vous de manger tranches de bifteck à cause de votre prothèse?	16. ☐☐☐
extrêmement difficile _____ Pas du tout difficile	
S'il vous plaît indiquer combien il est difficile pour vous de manger des pommes crues en raison de votre prothèse?	17. ☐☐☐
extrêmement difficile _____ Not at all difficult	
S'il vous plaît indiquer combien il est difficile pour vous de manger de la laitue à cause de votre prothèse?	18. ☐☐☐
extrêmement difficile _____ Not at all difficult	
8. La fonction	
En général, c'est votre nourriture bien mâchés avant d'avaler?	19. ☐☐☐
mal mâché _____ Très bien mâchés	
Morceaux de pain blanc frais sont bien mâchés avant d'avaler?	20. ☐☐☐
mal mâché _____ Très bien mâchés	
Morceaux de fromage à pâte sont bien mâchés avant d'avaler?	21. ☐☐☐
mal mâché _____ Très bien mâchés	
Morceaux des carottes crues sont bien mâchés avant d'avaler?	22. ☐☐☐
mal mâché _____ Très bien mâchés	
Morceaux de tranches de bifteck sont bien mâchés avant d'avaler?	23. ☐☐☐
mal mâché _____ Très bien mâchés	

Morceaux de pomme crue sont bien mâchés avant d'avaler? 24. ☐☐☐

mal mâché _____ Très bien mâchés

Morceaux de laitue sont bien mâchés avant d'avaler? 25. ☐☐☐

mal mâché _____ Très bien mâchés

9. Condition buccale 26. ☐☐☐

En général, êtes-vous satisfait de votre condition buccale?

Not at all satisfied _____ Extremely satisfied

27.

Croyez-vous que votre état de santé bucco-dentaire a un effet négatif sur votre santé en général?

Non ○0 Oui ○1

Si oui, pourquoi?

28.

****

Y at-il un quelconque problème avec votre prothèse supérieure ou inférieure que vous souhaitez signaler?

Non ○0 Oui ○1

Si oui, s'il vous plaît, décrire?

Appendix II: Ethics approval

Centre universitaire de santé McGill
McGill University Health Centre

Center for Applied Ethics

June 16, 2014

Comité d'éthique Génétique et populations Biomédicale D
a/s Mme Esther Boyle

Research Ethics Board Genetics/Population Research/ Gen Investigator Initiated Studies
Biomedical D
c/o Ms. Esther Boyle

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Dr. Rubens Albuquerque
McGill Faculty of Dentistry
3640 University Street
Room M/64

RE: 12-452 BMD entitled "Success with computer generated versus cast metal-frames for removable partial dentures: A crossover clinical trial."

Dear Dr. Albuquerque:

We have received an Application for Continuing Review of the Montreal General Hospital Biomedical D Research Ethics Committee for the research study referenced above and the report was found to be acceptable for ongoing conduct at the McGill University Health Centre.

At the MUHC sponsored research activities that require US federal assurance are conducted under Federal Wide Assurance (FWA) 00000840.

The re-approval for the study was provided via expedited review of the Chairman on June 16, 2014. It is noted in your report that MUHC recruitment is complete, and that the data is in the final analysis. A total of five (5) subjects have been enrolled in the study.

All research involving human subjects requires review at a recurring interval. Please note that it is the responsibility of the principal investigator to submit an application for Continuing Review to the REB prior to the expiration of approval, to comply with the regulation for continuing review of "at least once per year". However, should the research conclude for any reason prior to the next required review, you are obliged to submit a Termination Report to the Committee once the study analysis is complete to give an account of the study findings and publication status.

RE-APPROVAL	**JUNE 16, 2014**
EXPIRATION	**JUNE 15, 2015**

Should any revision to the research, or other unanticipated development occur prior to the next required review, you are obligated to report in writing promptly to the REB. It is not permitted by regulation to initiate a proposed study modification prior to REB approval.

Sincerely,

Michael Thirlwell, M.D.
Chairman
BMD Research Ethics Board
McGill University Health Centre

February 23, 2016

Dr. Faleh Tamimi
Dentistry
McGill University Health Centre

RE: 13-406 GEN entitled "Assessing the perception of laypeople and dentists of tooth color's esthetic for different skin tones."

Dear Dr. Tamimi:

We have received an Application for Continuing Review of the aforementioned study at the McGill University Health Centre.

We are pleased to provide you with re-approval, via expedited review by the Co-Chairman on February 23, 2016, to continue the conduct of your study at the McGill University Health Centre. A total of forty (40) subjects have been enrolled in the study since the study was initiated.

We would also like to take this opportunity to remind you that:

- It is the responsibility of the principal investigator to submit an application for Continuing Review to the REB prior to the expiration of approval, and trust that you appreciate the importance of maintaining research activities at the MUHC in compliance with regulatory codes.
- In absence of valid research ethics approval, the study data originating during the time of lapsed approval cannot be used for this study. If you wish to use this data, subjects must be re-contacted for consent to use the data collected during the period of lapsed ethics approval.
- Should the research conclude for any reason prior to the next required review, you are required to submit a Termination Report to the Committee once the data analysis is complete to give an account of the study findings and publication status.

RE-APPROVAL	**FEBRUARY 23, 2016**
EXPIRATION	**FEBRUARY 22, 2017**

Should any revision to the research or other unanticipated development occur prior to the next required review, please advise the REB promptly and prior to initiating a proposed revision.

We trust this will prove satisfactory to you.

Sincerely,

Dr. Terry Chow (*electronic signature*)
Co-Chairman
MUHC Research Ethics Board
McGill University Health Centre

March 25, 2016

Aliaa Al-khateeb
School of Dentistry

Re: Review of IRB Proposal #16-117

Dear Aliaa:

Your proposal entitled "Assessing the perception of laypeople and dentists for tooth color's esthetic for different skin tone," submitted to the University of the Pacific IRB, **has been approved**. Your project received an Exempt review.

You are authorized to work with 300 adults as human subjects. This approval is effective through March 31, 2017.

If you are not finished with data collection by the expiration date and/or finish your research we request that you file an *Active Protocol Status Report*. Please note we request the renewal form prior to the annual renewal/ deadline.

Procedural changes or amendments must be reported to the IRB, and no changes may be made without IRB approval except to eliminate apparent immediate hazards. To report a protocol revision, please complete the *Protocol Revision Form* and submit to the IRB Administrator at osp@pacific.edu .

Thank you, and best wishes for continued success in your studies.

Sincerely,
IRB Administrator

Valerie Andeola
Grants and Research Specialist